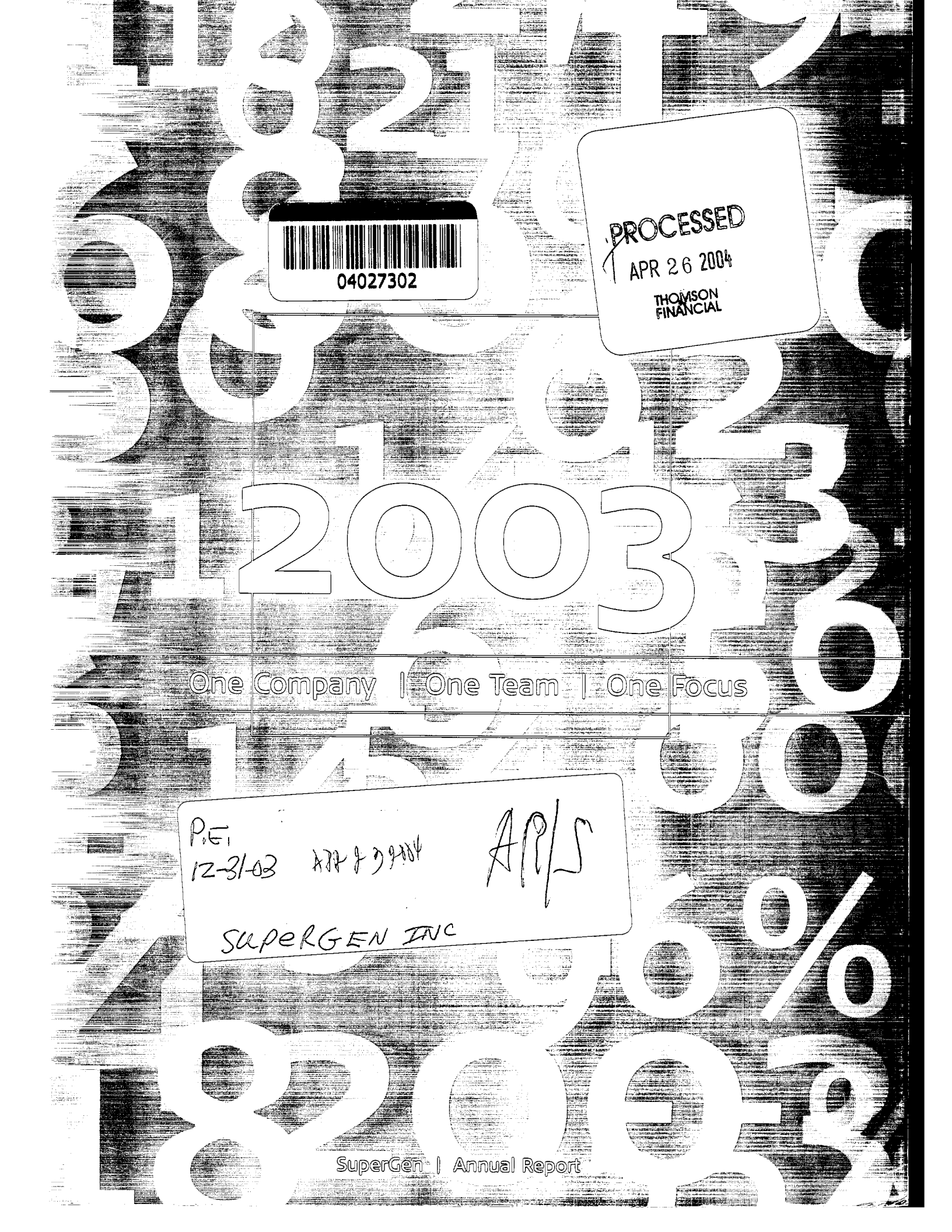
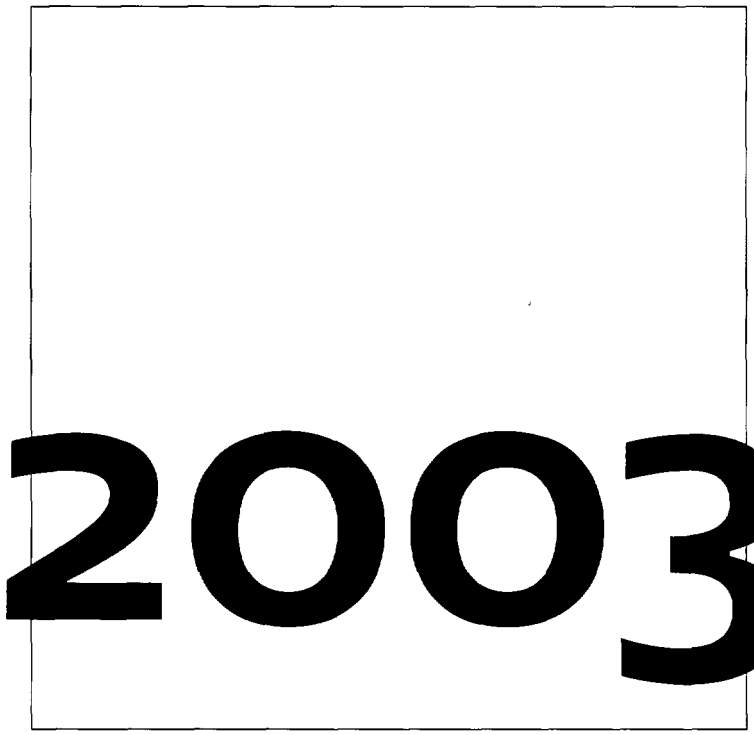
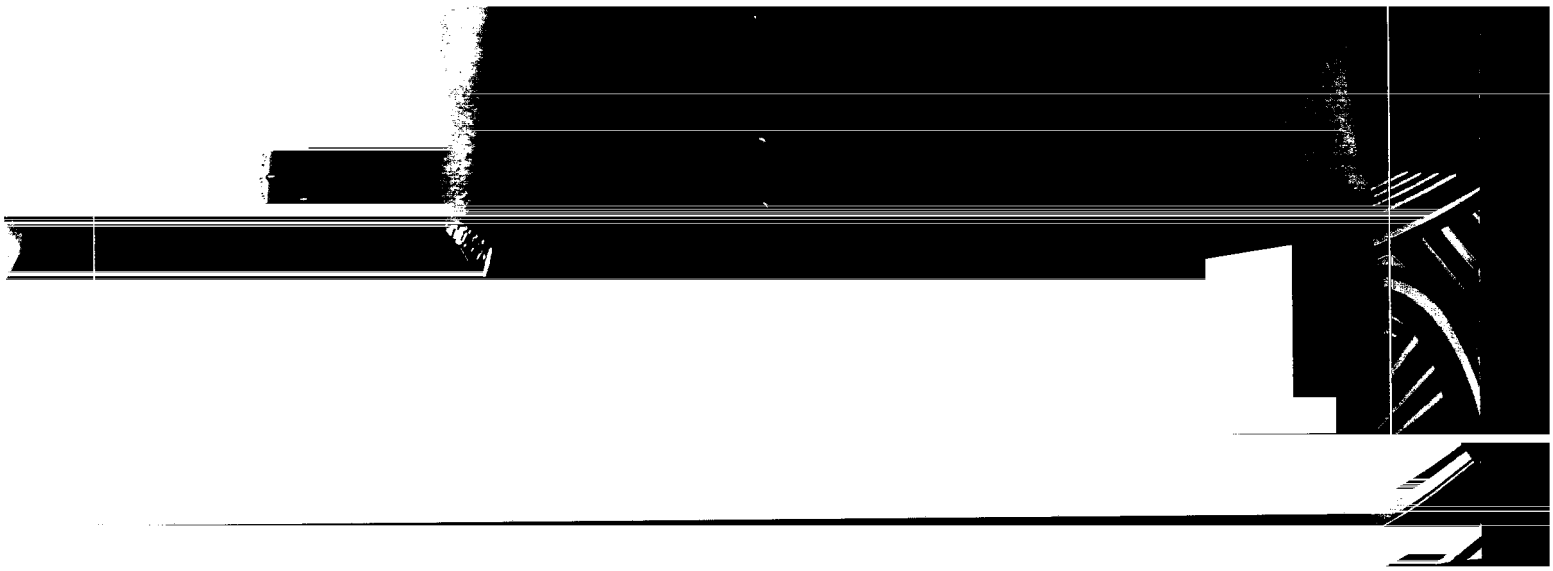




One Year

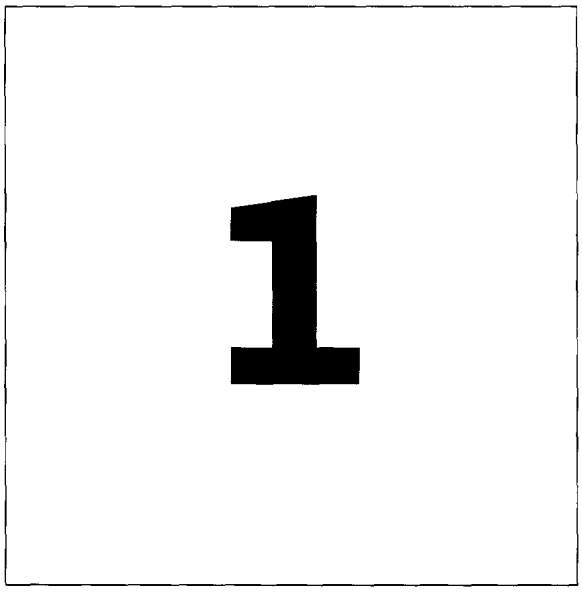
IN JUST ONE YEAR, SUPERGEN HAS MADE MAJOR ADVANCEMENTS WITH TWO OF THE COMPANY'S KEY INVESTIGATIONAL COMPOUNDS, ORATHECIN™ (RUBITECAN) CAPSULES AND DACOGEN™ (DECITABINE) FOR INJECTION. PIVOTAL PHASE III TRIALS WERE COMPLETED FOR BOTH PRODUCT CANDIDATES, AND THE PROCESS OF COMPILING AND SUBMITTING NEW DRUG APPLICATIONS (NDAs) WITH THE UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA) BEGAN. SHORTLY AFTER YEAR END, SUPERGEN SUBMITTED THE FINAL PORTION OF THE NDA FOR ORATHECIN AND THE COMPANY IS IN THE PROCESS OF COMPILING THE DACOGEN NDA. WITH ALL OF THE ACTIVITY REQUIRED TO COMPLETE THESE TWO TASKS, SUPERGEN NEVER LOST SIGHT OF THE PATIENTS WHO USE THE COMPANY'S DRUGS THAT ARE ON THE MARKET AND IN DEVELOPMENT.

THIS REPORT FOCUSES ON THE 2003 ACCOMPLISHMENTS OF SUPERGEN. AS YOU TURN THE PAGES OF THIS REPORT, YOU WILL SEE NUMBERS, BOTH LARGE AND SMALL, THAT REPRESENT SIGNIFICANT SUCCESSES FOR THIS RELATIVELY SMALL COMPANY. READ ON TO DISCOVER THE POWER OF SUPERGEN.



One Company

IN 2003, SUPERGEN TOOK THE FIRST STEPS TO BECOME A GLOBAL PHARMACEUTICAL COMPANY WITH A BROAD PORTFOLIO OF PROPRIETARY CANCER THERAPIES THAT TARGET A VARIETY OF SOLID TUMORS, HEMATOLOGICAL MALIGNANCIES AND BLOOD DISORDERS. AS THE YEAR 2004 UNFOLDS, SUPERGEN INTENDS TO SEEK FDA CLEARANCE FOR ORATHECIN, SUBMIT AN NDA FOR DACOGEN, DEVELOP THE MARKET FOR NIPENT® AND CONTINUE TO BUILD AND ADVANCE ITS CLINICAL PIPELINE. TO SUPPORT THESE EFFORTS, SUPERGEN INTENDS TO BEGIN TO EXPAND ITS SALES AND MARKETING INFRASTRUCTURE AND SHARPEN ITS COMMERCIAL FOCUS TO BRING ITS PRODUCTS TO MARKET IN THE UNITED STATES AND IN KEY EUROPEAN COUNTRIES. SUPERGEN INTENDS TO SEEK ONE OR MORE PARTNERSHIPS TO INTRODUCE ITS PRODUCTS IN ASIA. IN OTHER REGIONS OF THE WORLD, THE COMPANY INTENDS TO EMPLOY MARKETING ORGANIZATIONS AND DISTRIBUTORS.

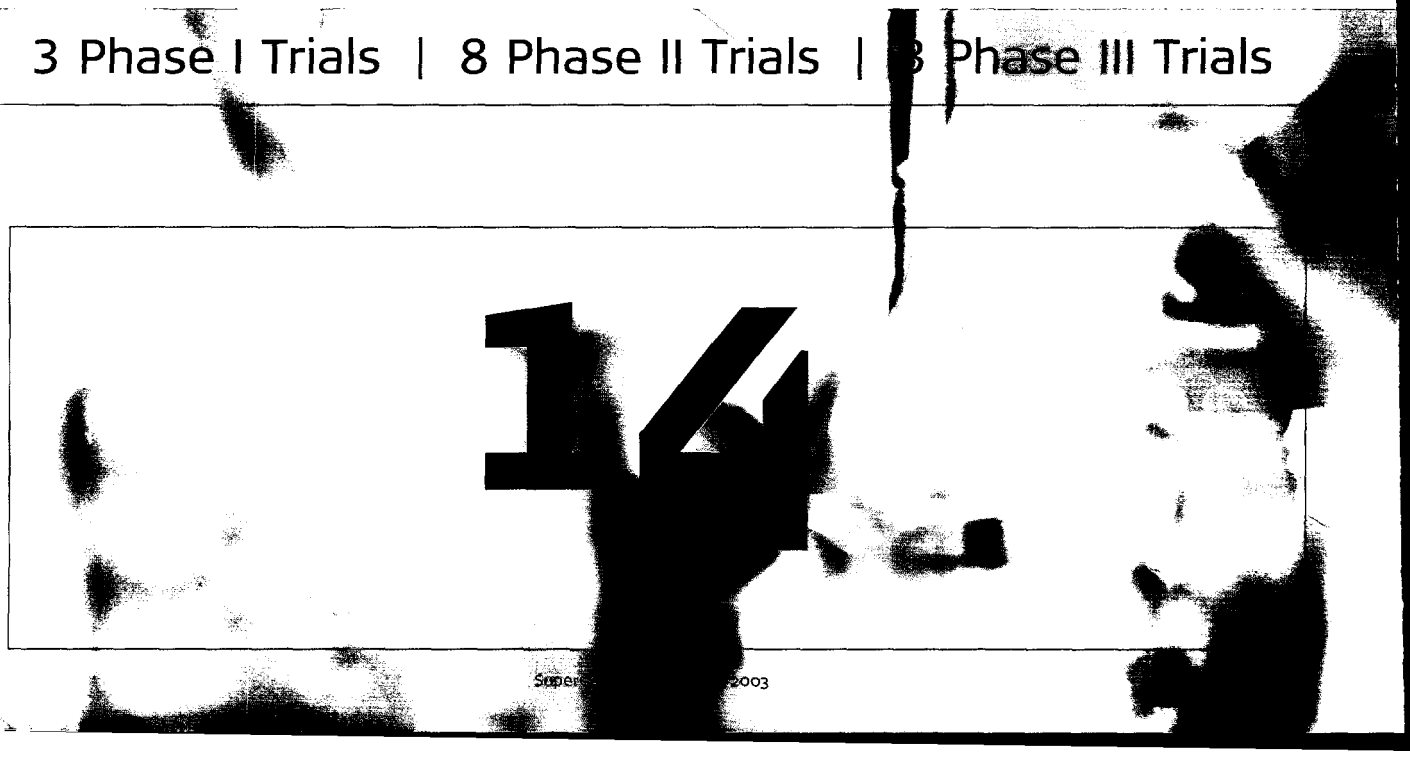


One Focus

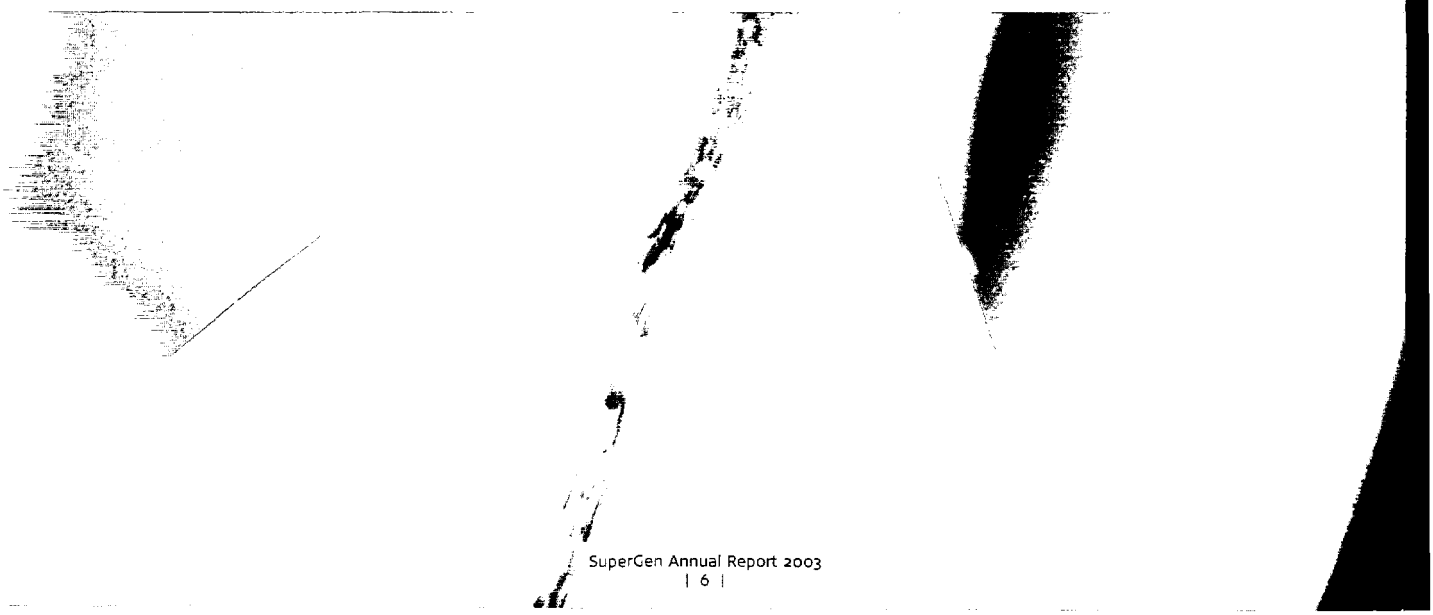
AS THE SECOND-LEADING CAUSE OF DEATH IN THE UNITED STATES, EVERY YEAR CANCER CLAIMS THE LIVES OF MORE THAN 500,000 PEOPLE IN THIS COUNTRY ALONE. WITH MORE THAN 1.3 MILLION NEW CASES OF CANCER EXPECTED IN THE U.S. IN 2004, THE NEED FOR NEW THERAPIES IS UNDENIABLE. WHILE THE MORTALITY RATE FOR HEART DISEASE HAS BEEN REDUCED BY MORE THAN 50% SINCE 1950, THE MORTALITY RATE FOR CANCER HAS NOT CHANGED IN MORE THAN 50 YEARS.* THIS UNMET MEDICAL NEED HAS BEEN RECOGNIZED BY THE FDA AND BY ALL OF THOSE WHO SUFFER FROM THIS DISEASE, THEIR FAMILIES, PHYSICIANS AND FRIENDS. SUPERGEN HAS RECOGNIZED THIS NEED AND HAS ONE FOCUS – TO IMPROVE THE LIVES OF CANCER PATIENTS. *SOURCE – AMERICAN CANCER SOCIETY STATISTICS PRESENTATION 2004.

OVER THE PAST FIVE YEARS, SUPERGEN HAS CONDUCTED 14 CLINICAL TRIALS FOR ORATHECIN. PHASE I TRIALS HELP DEFINE THE BEST DOSE AND SCHEDULE OF A DRUG THAT CAN BE SAFELY ADMINISTERED. PHASE II TRIALS DETERMINE CLINICAL ACTIVITY; PATIENTS ARE GIVEN THE HIGHEST SAFE DOSE AND MONITORED TO MEASURE THE EFFECTS, BOTH POSITIVE AND NEGATIVE. PHASE III TRIALS COMPARE A NEW THERAPY TO CURRENTLY AVAILABLE TREATMENTS AND MEASURE DIFFERENCES IN BOTH SAFETY AND EFFICACY. THE CULMINATION OF THIS PROCESS IS AN NDA SUBMISSION TO THE FDA, IN WHICH THE DATA ARE THOROUGHLY REVIEWED BEFORE A COMMERCIALIZATION DECISION IS MADE. AS PART OF THE NDA FILING FOR ORATHECIN, SUPERGEN SUBMITTED MORE THAN 8,000,000 KILOBYTES OF DATA ELECTRONICALLY TO THE FDA – A FIRST FOR SUPERGEN.

3 Phase I Trials | 8 Phase II Trials | 3 Phase III Trials

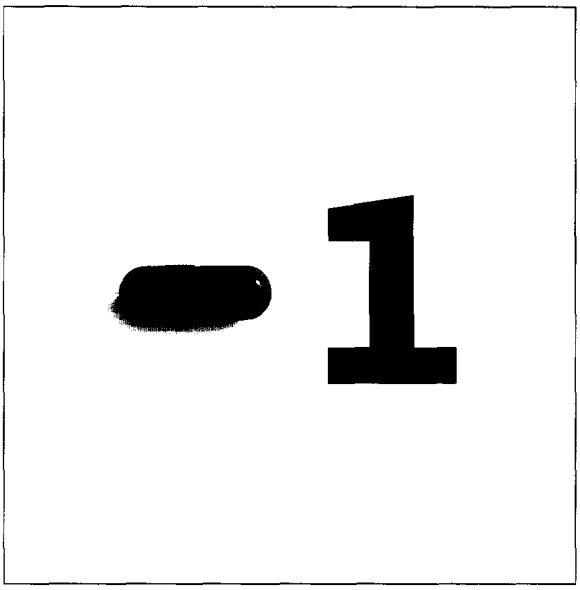


SUPERGEN COMMENCED ORATHECIN CLINICAL TRIALS IN 1998. SINCE THEN, MORE THAN 2,700 PATIENTS HAVE BEEN ENROLLED IN SUPERGEN-SPONSORED CLINICAL TRIALS. THE FDA GRANTED ORPHAN DRUG STATUS AND "FAST TRACK" DESIGNATION FOR ORATHECIN FOR THE TREATMENT OF PANCREATIC CANCER, WHICH HAS HELPED EXPEDITE THE DEVELOPMENT AND SUBMISSION PROCESS FOR THIS UNMET MEDICAL NEED. ORATHECIN WAS ALSO DESIGNATED AN ORPHAN DRUG FOR THE TREATMENT OF PANCREATIC CANCER IN EUROPE. IF APPROVED THIS YEAR, SUPERGEN WILL HAVE BROUGHT ORATHECIN TO MARKET IN JUST SIX YEARS, AND THE COMPANY ACCOMPLISHED THIS WHILE ADVANCING SEVERAL PRODUCTS THROUGH CLINICAL DEVELOPMENT AND COMPLETING A PIVOTAL PHASE III STUDY FOR DACOGEN.



One Pancreatic Cancer Cell

THE NEED FOR ORATHECIN STARTED WITH JUST ONE PANCREATIC CANCER CELL AND THE KNOWLEDGE THAT THIS IS ONE OF THE DEADLIEST CANCERS KNOWN TO MAN. THE AMERICAN CANCER SOCIETY ESTIMATES THAT 30,000 PEOPLE IN THE U.S. WILL DIE FROM PANCREATIC CANCER IN 2004 AND THAT ANOTHER 30,700 NEW CASES WILL BE DIAGNOSED. WITH A MORTALITY RATE OF 96%, NEW THERAPIES ARE DESPERATELY NEEDED. SUPERGEN BELIEVES THAT ORATHECIN, IF APPROVED FOR COMMERCIAL USE, WILL HELP IMPROVE THE LIVES OF PEOPLE SUFFERING FROM PANCREATIC CANCER.



One Treatment

ORATHECIN IS ONE TREATMENT THAT CAN POTENTIALLY IMPROVE THE LIVES OF THOSE SUFFERING FROM PANCREATIC CANCER. AFTER MORE THAN SIX YEARS IN DEVELOPMENT AT SUPERGEN, THE NDA FOR ORATHECIN WAS SUBMITTED TO THE FDA ON JANUARY 26, 2004. WHILE THE FDA STILL NEEDS TO FORMALLY ACCEPT AND REVIEW THE APPLICATION, SUPERGEN IS HOPEFUL THAT ORATHECIN WILL GAIN MARKETING CLEARANCE BY THE END OF 2004. IF APPROVED, THE INTRODUCTION OF ORATHECIN WOULD MARK THE FIRST AND ONLY ORAL PANCREATIC CANCER THERAPY APPROVED BY THE FDA.

MORE THAN 2,700 PATIENTS WERE TREATED AND EVALUATED THROUGHOUT THE ORATHECIN CLINICAL TRIALS. AS THE TRIAL PHYSICIANS MONITORED PATIENTS IN THEIR CARE, THEY KEPT DETAILED PATIENT RECORDS, INVOLVING MORE THAN 128,000 LAB RECORDS. AFTER 14 CLINICAL TRIALS, ALL OF THESE DATA WERE ANALYZED BY THE CLINICAL, REGULATORY AND QUALITY ASSURANCE TEAMS AT SUPERGEN, AND ARE BEING USED TO SUPPORT REGULATORY APPROVAL OF THE DRUG.

MORE THAN 680,000 CAPSULES WERE UTILIZED IN THE CLINICAL STUDIES OF ORATHECIN. ORATHECIN IS THE FIRST ORALLY ADMINISTERED CHEMOTHERAPY AGENT FOR PANCREATIC CANCER TO HAVE COMPLETED PHASE III CLINICAL TRIALS AND BEEN THE SUBJECT OF AN NDA SUBMISSION. A TYPICAL ORATHECIN PATIENT TAKES TWO TO THREE CAPSULES ONCE A DAY. ORAL ADMINISTRATION CAN ADD TO THE QUALITY OF PATIENTS' LIVES. WITH THE ORATHECIN THERAPY, PATIENTS CAN TAKE THE PRODUCT IN THE COMFORT OF THEIR OWN HOMES INSTEAD OF GOING TO THE HOSPITAL OR OUTPATIENT CLINIC FOR AN INTRAVENOUS INFUSION OF CHEMOTHERAPY.

One Team

DEAR STOCKHOLDER,

DYNAMIC, EXCITING, PRODUCTIVE, PROMISING – THESE FOUR WORDS BEST DESCRIBE THE YEAR 2003 FOR SUPERGEN. HAVING COMPLETED PIVOTAL PHASE III TRIALS FOR TWO OF OUR KEY INVESTIGATIONAL COMPOUNDS, WE ARE NOW POSITIONED TO EVOLVE INTO A GLOBAL PHARMACEUTICAL COMPANY, POSSESSING A SIZEABLE PORTFOLIO OF COMMERCIAL PRODUCTS AND A ROBUST DEVELOPMENT PIPELINE.

As we move into 2004, I am pleased to report that we have submitted the new drug application (NDA) for Orathecin™ (rubitecan) capsules with the United States Food and Drug Administration (FDA) and we are working diligently on compiling the NDA submission for Dacogen™ (decitabine) for injection. With both Orathecin and Dacogen having been granted fast-track status by the FDA, we hope to begin helping pancreatic cancer and myelodysplastic syndrome (MDS) patients worldwide in the near future.

In November 2003, an independent review of the results from the Phase III clinical program of Orathecin supported our findings of the drug's activity in patients with refractory pancreatic cancer who have failed prior treatments. The data have been reviewed by an independent third-party expert radiology review panel and were presented at the "Chemotherapy Foundation Symposium XXI – Innovative Cancer Therapy for Tomorrow" in New York City by Howard A. Burris, III, M.D., Director of Drug Development at the Sarah Cannon Cancer Center in Nashville, Tenn. Dr. Burris believes that these data suggest Orathecin may offer clinical benefits to pancreatic cancer patients with no current therapeutic options.

EVOLUTION INTO A GLOBAL PHARMACEUTICAL COMPANY

To successfully evolve into a global pharmaceutical company, there are several strategic initiatives that need to be executed during 2004. These initiatives are all based on the submission and acceptance of both the Orathecin and Dacogen NDAs, and, hopefully, ultimate marketing clearance of both products by regulatory agencies around the world. Although we have the utmost confidence in both of these drugs, we must remember that making a submission and having that submission accepted for filing is not a guarantee that the products will be approved. Both submissions will be heavily scrutinized by the FDA before a decision is made.

Given SuperGen's thrust to commercialization, it is apparent that we need to build the commercial development and sales and marketing infrastructures to bring these products to market and maximize awareness of these products if approval is received. We are fortunate to have a commercial team in place with an average of 20 years of individual experience in the sales and marketing of anticancer pharmaceutical products. Our plan is to build a presence in the U.S. and five key European countries, with a combination of a direct sales force and the development of other distribution channels. We anticipate partnering and establishing distribution channels to bring our products to Japan and other regions worldwide.

IMPORTANCE OF PIPELINE

As we build the infrastructure to commercialize Orathecin, we cannot overlook the importance of a robust development pipeline with several potential commercial products on deck. In our current portfolio, Dacogen holds the most promise – research has shown that Dacogen is active in multiple indications, including sickle cell anemia and chronic myelogenous leukemia. At the American Society of Hematology conference in December, 2003, 18 abstracts and presentations were made supporting the activity of Dacogen in a variety of indications. In 2004 and beyond, we intend to begin seeking indication and labeling expansion for Orathecin and Dacogen, while simultaneously infusing our pipeline with additional development-stage products.

SUPERGEN HAS SEVERAL PRODUCTS ON THE MARKET, ONE NDA SUBMITTED WITH THE FDA, ONE NDA BEING COMPILED, A ROBUST PIPELINE OF CLINICAL- AND PRECLINICAL-STAGE DRUGS IN DEVELOPMENT, AND AN INCREDIBLY TALENTED TEAM IN PLACE TO LEAD OUR COMPANY THROUGH ITS NEXT STAGE OF GROWTH.

THE FUTURE

We have broad ambitions for 2004 and beyond. Although I took over the reigns of this fine company on January 1 of this year, I have been involved in SuperGen since the company's founding and have great confidence in our future. Dr. Joseph Rubinfeld and the team behind him built an impressive company in just 12 years. SuperGen has several products on the market, one NDA submitted to the FDA, one NDA being compiled, a robust pipeline of clinical- and preclinical-stage drugs in development, and an incredibly talented team in place to lead the company through this next stage of growth. As chief executive officer, I plan to build on this foundation and take SuperGen to the next level as a truly global pharmaceutical company. As a member of our board of directors and as SuperGen's chief scientist and chairman emeritus, Dr. Rubinfeld will assist us with product identification and acquisition and will continue to be a resource to our company. I want to personally thank Joe for his hard work and dedication, and for making SuperGen what it is today.

Thank you for your support.

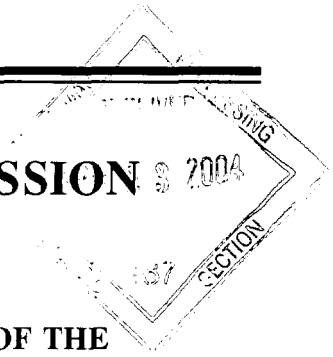
Sincerely,

James S. J. Manuso, Ph.D.

President and Chief Executive Officer

Financials

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549



FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended December 31, 2003

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 0-27628

SUPERGEN, INC.
(Exact name of registrant as specified in its charter)

Delaware	**91-1841574**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification Number)
4140 Dublin Blvd., Suite 200, Dublin, CA	**94568**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(925) 560-0100**

Securities registered pursuant to Section 12(b) of the Act: **None**
Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.001 par value per share
(Title of Class)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether Registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

The aggregate market value of the voting stock held by non-affiliates of the Registrant (based on the closing sale price of the Common Stock as reported on the Nasdaq Stock Market on June 30, 2003, the last business day of the Registrant's most recently completed second fiscal quarter) was approximately $178,517,248. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The number of outstanding shares of the Registrant's Common Stock as of the close of business on February 27, 2004 was 38,470,198.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III incorporate by reference information from the definitive proxy statement for the Registrant's Annual Meeting of Stockholders to be held on May 6, 2004.

SUPERGEN, INC.

2003 ANNUAL REPORT ON FORM 10-K

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Special Note Regarding Forward-Looking Statements

Our disclosure and analysis in this report contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, and within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements provide our current expectations or forecasts of future events. When we use the words "anticipate," "estimate," "project," "intend," "expect," "plan," "believe," "should," "likely" and similar expressions, we are making forward-looking statements. In particular, these include, but are not limited to, statements relating to future product developments and launches, including our clinical trials for Orathecin, Dacogen, Nipent and our other products and product candidates; whether the FDA will accept for filing our new drug application for Orathecin; the final results of the Phase III study of Dacogen for MDS; the timing of filing of a new drug application for Dacogen; sales growth; operating performance; our estimated capital needs; and potential market sizes. Our actual results could differ materially from those predicted in the forward-looking statements as a result of risks and uncertainties including, but not limited to, delays and risks associated with conducting and managing clinical trials, developing our products and obtaining regulatory approval; ability to establish and maintain collaboration relationships; competition; ability to obtain funding; adverse changes in the specific markets for our products, and ability to launch and commercialize our products. Certain unknown or immaterial risks and uncertainties can also affect our forward-looking statements. Consequently, no forward-looking statement can be guaranteed and you should not rely on these forward-looking statements.

The forward-looking statements reflect our position as of the date of this report, and we undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, or other filings. Also note that we provide a cautionary discussion of risks and uncertainties relevant to our business under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations—Factors Affecting Future Operating Results" in this report. These are currently known and material risks that we believe could cause our actual results to differ materially from expected and historical results. Other unknown and immaterial risks besides those listed in this report could also adversely affect us.

PART I

ITEM 1. BUSINESS.

We incorporated in March 1991 as a California corporation and changed our state of incorporation to Delaware in May 1997. Our executive offices are located at 4140 Dublin Blvd., Suite 200, Dublin, CA, 94568 and our telephone number at that address is (925) 560-0100. We maintain a website on the internet at www.supergen.com.

Overview

We are a pharmaceutical company dedicated to the development and commercialization of therapies for solid tumors, hematological malignancies and blood disorders. Currently, we have three key compounds that are the primary focus of our efforts: Orathecin™ (rubitecan) capsules, Dacogen™ (decitabine) injection and Nipent® (pentostatin for injection). On January 26, 2004, we submitted a New Drug Application, or NDA, under accelerated approval procedures with the Food and Drug Administration, or FDA, for Orathecin for the treatment of refractory pancreatic cancer patients. If accepted for filing by the FDA, our submission will likely receive expedited substantive review within six months of the filing date. We are compiling and validating the results from our Phase III study of Dacogen for the treatment of myelodysplastic syndrome, or MDS, and if the study results are positive, anticipate commencing submission of the initial modules of a "rolling" NDA in 2004. The FDA granted us "fast track" designation for Dacogen for the treatment of MDS in May 2003, which means the FDA

will facilitate and expedite the development and review of the submission. Nipent is approved by the FDA for the treatment of hairy cell leukemia and is marketed by us in the United States. We have completed several Phase IV clinical trials, or post-marketing trials, and continue to conduct trials intended to expand Nipent's potential use beyond the treatment of patients with hairy cell leukemia to indications including chronic lymphocytic leukemia, or CLL, non-Hodgkin's lymphoma, or NHL, and graft-versus-host disease, or GvHD. We have commercialization rights for each of these compounds, and intend to market them directly in the United States through our sales force, and either directly or indirectly in international markets.

Strategy

We commercialize products by pursuing a strategy of identifying and acquiring pharmaceutical compounds in the late stages of development, which allows us to minimize the time, expense and technical risk associated with drug research. Rather than engage in discovery research to obtain lead compounds, we license or acquire rights to compounds that have shown initial efficacy in humans or in a model relevant to a particular disease at the pre-clinical or early clinical stages of development. Our primary objective in the pursuit of this strategy is to be a leading supplier and developer of therapies for solid tumors, hematological malignancies and blood disorders. Key elements of our strategy include:

Expanding commercialization of our current products and launching each new product when approved by the FDA. In preparation for the potential approval of Orathecin by the FDA, we intend to focus significant resources on commercialization efforts associated with Orathecin and the subsequent launch of Orathecin as a marketed drug. As part of the commercialization effort, we intend to:

- hire additional sales, marketing and medical affairs personnel;
- develop and implement a pancreatic cancer indigent support program;
- develop and implement Phase IV clinical trials to explore additional combination and single agent uses for the product;
- develop and implement a physician, pharmacist and nursing education program to fully understand the impact and advantages of treating cancer patients in the home;
- develop and produce collateral material regarding the appropriate uses of Orathecin; and
- further develop and refine marketing plans with respect to Orathecin.

It is our intent to continue to increase our presence within the oncology marketplace through our commercialization initiatives, and we believe such efforts will also benefit our existing product, Nipent, and the pre-marketing preparation for Dacogen, if approved.

Expanding our sales and market penetration of the therapeutic anti-cancer market. We have endeavored to establish a leadership position in the market of hematological products. This market exists within the overall anti-cancer market. We are expanding our sales and marketing organization in the hematology space and expanding our brand into solid tumors to support commercialization of our new products, if approved. This expansion, which is being pursued in concert with our pre-marketing commercialization investments for Orathecin, primarily entails increasing the number of direct sales representatives we employ to call on oncologists and hematologists. The expansion also entails additional investment in marketing and branding initiatives to extend our name recognition further into the therapeutic anti-cancer market.

Globalizing our commercial presence. We believe that the global market opportunity for our products is meaningfully greater than the market opportunity in the United States alone. Therefore, as more of our products are approved for marketing in the United States, we intend to penetrate the worldwide market for anti-cancer products. The establishment of our subsidiary, EuroGen

Pharmaceuticals, Ltd., or EuroGen, is an initial step in this strategy, intended to create a presence for our products in five major countries of the European Union, or EU, directly. EuroGen is primarily a registration, sales and marketing organization, and Larry Johnson, its president and chief executive officer, has expertise in starting, growing and developing market share outside of the United States. Recently, EuroGen filed registration documentation to sell mitomycin and paclitaxel, and anticipates filing registrations for Orathecin and Dacogen. EuroGen is not expected to penetrate all European markets in the near future. The markets for anti-cancer products in the United Kingdom, Germany, France, Italy and Spain represent approximately 80 percent of the current anti-cancer market in Western Europe. We expect EuroGen to be generating revenue by the end of 2004 from sales of our products. We intend to penetrate other areas outside of the United States through partners and distributors.

Capitalizing on our existing clinical expertise and regulatory development to maximize the commercial value of our products. We intend to expand potential applications of our products both within existing labeling for our products and through supporting physician-initiated interest in clinical trials in therapeutic areas beyond our products' approved indications. This expansion entails managing numerous additional clinical studies and regulatory interactions for our key products. This process is complex whether it is conducted through our clinical department for formal label expansion or whether the trials are supported and managed through our Professional Services department. Over 20 physicians have initiated clinical studies with Nipent that are currently being managed by our Professional Services department for a wide range of diseases. Companies are open to working with us because of our corporate expertise with the developmental, regulatory and marketing aspects of maximizing the value of products in this market segment. We believe this core competency is an asset that will continue to draw other developmental products to us. We believe our clinical development experience serves to increase the value of our product portfolio.

Licensing or buying rights to later stage compounds. We identify and seek to license or buy rights to products or compounds that are in human clinical development or already marketed. We then seek to enhance and complete the product development. We believe that our approach minimizes the significant financial investment required by discovery research and reduces the risk of failure in developing a commercially viable product. Orathecin, Dacogen and Nipent were each acquired through this process. We believe our ability to navigate products through clinical development, the FDA and other regulatory agencies makes us a more attractive partner for companies seeking to sell or license later stage products or compounds.

Summary of Products and Products in Development

Orathecin

Orathecin is an oral chemotherapy compound in the camptothecin class, licensed from the Stehlin Foundation for Cancer Research, or Stehlin, in 1997. Orathecin is a second-generation topoisomerase I inhibitor that causes single-strand breaks in the DNA of rapidly dividing tumor cells. Based on our developmental program and clinical trial results, we believe that Orathecin may have significant advantages over many existing anti-cancer drugs, including efficacy, side effect profile and oral dosing. In particular, we believe that inhibition of bone marrow function is low, due in part to Orathecin's dosing schedule, which provides for a cycle of five days of administration followed by two days of recovery. In clinical trials, the observed side effects were mild to moderate hematological toxicities, low-grade cystitis, infrequent and mild hair loss and gastrointestinal disorders. As an oral drug that can be taken at home, we believe treatment with Orathecin would be more convenient, may reduce overall healthcare costs, and may provide patients with an improved quality of life.

On January 26, 2004, we submitted an NDA with the FDA in support of Orathecin for the treatment of patients with refractory pancreatic cancer. If approved by the FDA, we believe that

Orathecin is a key drug that may be used in the treatment of a broad array of solid tumors and hematological malignancies. Because we submitted our NDA under accelerated approval procedures, if it is accepted for filing by the FDA, our NDA will receive expedited substantive review within six months of the filing date. Orathecin received orphan drug designation for pancreatic cancer in both the United States and Europe, which may provide us with seven years of marketing exclusivity in the United States and ten years of marketing exclusivity in Europe, if Orathecin is approved by regulatory authorities for this disease. Similar marketing exclusivity is available in Japan.

Pancreatic Cancer

Pancreatic cancer causes more than 75,000 deaths per year globally. Based on a 1988-1992 study by the National Cancer Institute, or NCI, pancreatic cancer accounts for only two percent of all newly diagnosed cancers in the United States each year, but results in five percent of all cancer deaths. The most commonly used therapies to treat pancreatic cancer include 5-FU and gemcitabine.

In May 2000, we presented data from a Phase II study of Orathecin at a meeting of the American Society of Clinical Oncology. These data support Orathecin's efficacy in pancreatic cancer patients who had failed previous chemotherapy. Of the 45 patients with measurable disease, ten experienced either a reduction in the size of their tumor or disease stabilization, meaning that the tumor did not grow. After starting Orathecin treatment, the median survival for these ten patients was approximately ten months. Four of them survived more than 12 months and two survived more than 24 months.

To date, over 2,700 patients in our clinical studies have been treated with Orathecin. We believe that our Orathecin clinical program is the largest regulatory registration program ever undertaken in pancreatic cancer. In 1998, we commenced three stand-alone Phase III clinical trials with Orathecin for treatment of advanced pancreatic cancer. The three studies are: "Gemcitabine refractory," where patients who failed treatment with gemcitabine were randomized to either Orathecin or 5-FU; "Chemotherapy refractory," where patients who failed multiple types of chemotherapy were randomized to either Orathecin or the physician's best choice therapy; and "Chemotherapy naïve," where patients who had no prior chemotherapy were randomized to Orathecin or gemcitabine. In the FDA's summary basis of approval, the program sizes for gemcitabine and 5-FU, were as follows: gemcitabine had 126 patients in front-line use and 63 patients in second-line use, and 5-FU was approved on data from 20 pancreatic cancer patients. The primary endpoint of these trials was survival. The patient populations for the Orathecin Phase III clinical studies are as follows:

Protocol Description of Three Stand-Alone Phase III Studies	Enrollment Completed	Patients Enrolled
Gemcitabine refractory	February 2001	448
Chemotherapy refractory	June 2001	409
Chemotherapy naïve	October 2001	994

Given the large scale of the Orathecin clinical program and the inherent uncertainties associated with clinical trials of such magnitude and complexity, the data and statistical analysis from these trials may not support regulatory approval. For example, the design of these trials allowed patients who initially were being treated with gemcitabine or other therapies to cross over to treatment with Orathecin. At the time the trials were designed, we believed that the percentage of patients who would cross over for treatment with Orathecin would be in the range of ten percent to 20 percent of the total enrolled patients. The number of patients in our trials who actually crossed over to treatment with Orathecin significantly exceeded the number anticipated and was nearly 50 percent in two of our Phase III studies. The extent of this cross over has negatively affected the statistical analysis of the study with respect to the overall survival analysis, making it difficult to determine if the product is efficacious with respect to survival.

In May 2003, we announced data from one of our Phase III studies of Orathecin in patients with advanced pancreatic cancer, most of whom had previously failed two or more chemotherapy treatments. The study randomized 409 patients to either Orathecin or "best medical therapy." The primary study end-point was overall survival with secondary end-points, including tumor response and time to disease progression. We did not meet the primary end-point, although we did meet two of the secondary end-points. The two secondary end-points were independent of a cross-over effect whereas the primary end-point was not. It remains uncertain whether the released data, and the data from our other clinical trials, will be sufficient to support regulatory approval for Orathecin, and additional trials may be required before we can obtain regulatory approval.

Other Potential Indications

In addition to studies relating to pancreatic cancer, pre-clinical studies have shown Orathecin to be active in more than 30 human and animal tumor models in indications such as breast, lung, colorectal, ovarian, gastric and prostate cancers, as well as sarcomas. We are pursuing numerous Phase I/II trials using Orathecin both as a single therapeutic agent and in combination with other anti-cancer agents in solid tumors and hematological malignancies.

In addition, we are currently conducting pilot studies using Orathecin in combination with other chemotherapeutic agents. In studies to date, Orathecin has not exhibited significant cardiac, pulmonary, hepatic or renal toxicities that often limit the acute and/or chronic dosages of several chemotherapeutics. The primary dose-limiting toxicities associated with Orathecin are hematologic and gastrointestinal disorders.

Dacogen

Dacogen, a pyrimidine analog that decreases the amount of methylation at certain DNA sites, is an active therapeutic product that we acquired from Pharmachemie in September 1999. Aberrant DNA methylation has been implicated as a fundamental factor in the development of all cancers. Researchers have determined that an increase in specific methylation of DNA can result in blocking the activity of genes, thereby reducing the degree of cellular antigen expression and potentially causing chemotherapy resistance. In clinical studies, researchers have demonstrated that Dacogen can reverse the methylation of DNA, potentially leading to re-expression of genes and a resulting re-differentiation and maturation of the cancer cells back to pre-cancer levels. Researchers have also shown that Dacogen treatment may reverse drug resistance by restoring the sensitivity of tumors to treatment by drugs such as cisplatin.

Myelodysplastic Syndrome

MDS is a bone marrow disorder characterized by the production of abnormally functioning, immature blood cells. According to the American Cancer Society, there are an estimated 10,000-20,000 new cases of MDS in the United States each year. In the majority of afflicted patients, MDS results in death from bleeding and infection. In other patients, MDS can transform to acute myeloid leukemia, or AML, a disease with a high mortality rate.

In multiple Phase II studies in Europe, researchers demonstrated that Dacogen is active and potentially efficacious for treating patients with MDS. Based on positive results from these European Phase II studies, we conducted a randomized Phase III study at over 20 cancer centers in the United States with 170 patients, that compared Dacogen to best supportive care for MDS. The primary end-point was time to AML or death. This Phase III trial was designed to support regulatory approval of Dacogen for the treatment of patients with MDS in the United States. We completed an interim analysis of the first 45 patients from the Phase III study, which indicated increased time to acute AML or death (median 105 days versus 92 days $p=0.036$). However, because this interim analysis is based on limited preliminary data, we cannot assure you that it is predictive of the final results of the study, that

the final results of the study will not be materially worse, or that we will not be required to conduct additional large-scale clinical studies to support FDA approval of Dacogen. If the Phase III final results are positive, we anticipate submitting the initial modules of a "rolling" NDA to the FDA in 2004. Dacogen received orphan drug designation in the United States and Europe, which may provide us with seven years of marketing exclusivity in the United States and ten years marketing exclusivity in Europe, if Dacogen is approved by regulatory authorities for MDS. In addition, the FDA has granted us "fast track" designation for Dacogen. However, the FDA approval process may take a significant amount of time and Dacogen may not be approved.

Other Potential Indications

In addition to MDS, we believe Phase I/II studies demonstrate that Dacogen may be active in a variety of other hematological malignancies such as AML and refractory chronic myelogenous leukemia, or CML. We are currently conducting a multi-center Phase II study with Dacogen for the treatment of refractory CML in patients who have failed previous front-line therapy. Phase I results also suggest that Dacogen may be useful for treatment of non-malignant diseases such as sickle cell anemia, for which we have initiated a Phase II clinical program. Dacogen received orphan drug designation from the FDA for sickle cell anemia in September 2002, which may provide us with seven years of marketing exclusivity in the United States if Dacogen is approved by the FDA for this indication.

The Dacogen clinical and scientific program has been integrated into an active Clinical Research and Development Agreement, or CRADA, with the NCI. Pursuant to the CRADA, we will supply Dacogen for pre-clinical and clinical trials that will be managed by the NCI and that will focus primarily on the treatment of solid tumors.

Nipent

Nipent inhibits a key enzyme in the DNA synthesis process and results in cytotoxicity, primarily in lymphocytes, with little other known effect on normal tissue. We acquired Nipent from the Parke-Davis division of the Warner-Lambert Company (Pfizer) in 1996. We believe that Nipent's most unique feature is its selectivity for lymphocytes, which has created an interest in this product for the treatment of cancers of the lymphoid system and other hematologic malignancies. Nipent has been our principal source of revenue since 2000.

Hairy Cell Leukemia

We are selling Nipent directly in the United States for the treatment of hairy cell leukemia, a type of B-lymphocytic leukemia. Warner-Lambert retained a worldwide, royalty-free license to sell Nipent, but has agreed not to sell the drug in North America through September 2006. In addition, in 1997 Warner-Lambert agreed to buy Nipent from us for all of its sales outside the United States through October 2004. We are permitted to sell Nipent outside of North America for treatment of diseases other than cancer until September 2006, at which time we may sell the drug worldwide for any disease. We are currently in discussions to acquire the distribution and marketing rights to Nipent in Europe.

Other Indications

Phase IV trials suggest that Nipent may have activity in a variety of other hematologic cancers. We are conducting Phase IV studies for treatment of hematological malignancies and disorders, such as CLL, NHL, and cutaneous and peripheral T-cell lymphomas.

In addition, Nipent has shown activity in various autoimmune diseases, including GvHD, bone marrow transplantation and multiple sclerosis. We believe that the United States markets for GvHD and various autoimmune diseases is larger than the market for hairy cell leukemia. We are conducting

Phase I clinical trials in autoimmune conditions and Phase II trials in GvHD, and developing an oral formulation of Nipent, which may be suitable for more chronic administration.

Other Products and Product Candidates

In addition to our three key compounds, Orathecin, Dacogen and Nipent, we have the following products and product candidates:

Product Category	Compound	Indication or Intended Use	Therapeutic Category	Regulatory Status
Generic Anti-Cancer Products	Mitomycin	Solid tumors	Cancer	Marketed
	Daunorubicin	Acute leukemias	Cancer	Approved
	Paclitaxel	Solid tumors	Cancer	ANDA filed
Non-Pharmaceutical Product	Surface Safe®	Surface Decontaminate		Marketed
Formulation Products	Mitozytrex	Solid tumors	Cancer	Approved
	Inhaled Orathecin	Solid tumors	Cancer	Phase II
	Inhaled paclitaxel	Solid tumors	Cancer	Pre-clinical
	Partaject busulfan	Neoplastic meningitis/ bone marrow transplant	Cancer	Phase I/II
	Partaject Orathecin	Solid tumors	Cancer	Pre-clinical
	CZ 112	Solid tumors	Cancer	Phase I
	Cremophor-free paclitaxel	Solid tumors	Cancer	Pre-clinical
Product Candidates	Avicine	Therapeutic Vaccine	Cancer	Phase II
	VEGF	Anti-angiogenesis	Cancer	Pre-clinical

Generic Anti-Cancer Products

We have developed generic versions of existing anti-cancer agents as part of our proprietary formulation product development efforts. We believe that the total estimated United States sales for generic anti-cancer products have decreased over the last few years due to increased competition. We also believe sales for these generics may continue to decrease as a result of competitive factors. These factors may include reductions in the per unit sales price, introduction of additional generics as well as other cancer drugs, new formulations for these drugs and the use of different therapies. Therefore, we currently intend to limit our development of generic products to those that either require minimal effort to submit an abbreviated new drug application, or ANDA, and obtain marketing clearance, or that offer significant market opportunities.

Mitomycin. We received approval of an ANDA for our generic mitomycin in 1998 for the treatment of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed. We are currently selling mitomycin in the United States.

Daunorubicin. We received approval of an ANDA for generic daunorubicin for a variety of acute leukemias in 2001. We are currently in the process of commercializing daunorubicin, and are continuing to explore marketing opportunities and/or marketing partners for this product.

Paclitaxel. We filed an ANDA for generic paclitaxel with the FDA in August 1998 and have filed a number of responses to letters from the FDA concerning our application. We anticipate an approval in 2004.

Non-Pharmaceutical Product

Surface Safe. Surface Safe is a two-step disposable towelette cleaning system used to decontaminate work surfaces where chemotherapeutic preparation is conducted, which we acquired from Aldorr, Inc., a medical technology development company, in July 1999. The first towelette contains chemicals recommended by the Centers for Disease Control and the Occupational Safety Health Administration to clean work surfaces. The second towelette is used to deactivate the chemicals used in the first towelette, in order to prevent damage to work surfaces through its potent oxidizing process.

Formulation Products

We have focused the application of our technologies to the development of improved formulations of existing anti-cancer agents, which will be marketed as brand name pharmaceuticals. We believe that incorporating our technologies with these compounds may result in products with improved delivery and/or administration. The development of these products is subject to the NDA approval process.

Mitozytrex. Our first product utilizing our formulation technology, Mitozytrex, which is a formulation of generic mitomycin, was approved by the FDA in November 2002 for use in the therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed. We cannot promote Mitozytrex as providing any injection site ulceration protection, nor can we promote any commercially viable increased stability, solubility or shelf life extension, as compared to generic mitomycin. We must develop and submit additional data to the FDA in NDA supplements and receive FDA approval for additional claims. We are currently exploring marketing opportunities and/or marketing partners for Mitozytrex.

Inhaled Cancer Drugs. In December 1999, we acquired worldwide licenses from Clayton Foundation for Research and its technology transfer organization, Research Development Foundation, to make and sell inhaled versions of formulations of paclitaxel and camptothecins, including Orathecin. Phase I clinical studies with inhaled Orathecin for the treatment of lung cancer and pulmonary metastatic disease have been completed at the M.D. Anderson Cancer Center and the Baylor College of Medicine and a Phase II study is under way.

Partaject Drug Delivery Technology. Partaject drug delivery technology is a drug delivery system that accommodates poorly water-soluble and water-insoluble compounds by encapsulating them with a fatty layer, known as a phospholipid. The Partaject technology involves coating particles of a drug that are of submicron or near micron size with a membrane-forming phospholipid layer, thereby permitting the creation of a suspension of the drug rather than a solution, and its intravenous injection without the use of potentially toxic solubilizing agents. As a result, we believe the Partaject technology may reduce toxicity created by other injectable forms of delivery mechanisms and potentially increase efficacy by facilitating delivery of compounds whose prior intravenous delivery was impractical because of solubility-related formulation difficulties.

Partaject products under development. Busulfan is currently marketed in an oral dosage form by GlaxoSmithKline for the palliative treatment of CML. It is used "off-label" as a bone marrow ablating agent prior to bone marrow transplants. In 1998, we completed a Phase I clinical trial of Partaject busulfan at both Johns Hopkins Oncology Center and Duke University Medical Center. A Phase I clinical trial in pediatric bone marrow ablation has been completed in 35 patients at St. Jude's Children's Hospital in Memphis.

Partaject busulfan is currently also being studied for intrathecal treatment of neoplastic meningitis with a Phase I/II study at Duke University Medical Center and a Phase I study with the Pediatric Brain Tumor Consortium.

We are also developing Partaject Orathecin, an intravenous formulation, which may be suitable for patients who cannot swallow an oral medication. This program is currently in pre-clinical development.

Oral Prodrug Delivery Technology—CZ 112. Oral prodrug delivery technology involves administering an inactive compound, known as a prodrug, which is absorbed in the digestive tract and is converted enzymatically to an active agent in the liver. Oral prodrug delivery technology could potentially enable the oral delivery of drugs that are otherwise only used in an intravenous formulation. The resulting active compounds may pass through the systemic circulation and act at peripheral sites. We are applying the oral prodrug delivery technology to compounds selected for their potential either to serve as oral delivery agents for systemically active chemotherapeutic or radio sensitizing drugs previously available only in intravenous form. CZ 112 is an oral prodrug for Orathecin we licensed from Stehlin in November 1999 after initial Phase I testing. We are currently completing additional pre-clinical tumor model studies prior to deciding to undertake further clinical development.

Cremophor-Free Paclitaxel. In January and October 2000, we were issued two United States patents for a cremophor-free formulation of paclitaxel. We were issued a third patent for an oral formulation in November 2001. We believe that these patents have important clinical and strategic implications as such a formulation obviates the need for pre-medication, which is currently required with the use of paclitaxel. We believe that the lack of pre-medication and an oral formulation will prove to be major competitive advantages in the paclitaxel market.

Product Candidates

Avicine. In July 2000, we acquired the sales and marketing rights in the United States to Avicine from AVI BioPharma, Inc., or AVI. Avicine is a therapeutic cancer vaccine in clinical development and is in Phase II trials for colorectal and pancreatic cancer.

VEGF (Anti-Angiogenesis). In February 2001, we licensed from Peregrine Pharmaceuticals, or Peregrine (formerly known as Techniclone Corp.) a platform drug-targeting technology known as Vascular Targeting Agent, or VTA. The licensed technology is related to Vascular Endothelial Growth Factor, or VEGF. The VTA technology is a proprietary platform designed to specifically target a tumor's blood supply and subsequently destroy the tumor with various attached therapeutic agents.

Proprietary Formulation Technology

We have developed several applications for our proprietary formulation technology, a platform technology that employs the use of an inert chemical excipient, cyclodextrin, combined with a drug. Most anti-cancer drugs are cytotoxic, and most must be administered intravenously. If a vein is missed on injection, the drug can leak to surrounding tissue, causing ulceration that sometimes requires plastic surgery to correct. Our proprietary formulation technology is designed to "shield" the drug from the injection site, thus helping to provide the patient protection from tissue ulceration. It may also increase the relative solubility of hard-to-dissolve anti-cancer drugs, hence potentially increasing its stability or shelf life. Each of these benefits must be supported by appropriate data and approved by the FDA as part of an NDA filing. We believe that such features, if approved by the FDA, will result in our formulation products having a significant competitive advantage over their counterparts currently on the market. In March 1994, we acquired exclusive worldwide rights to the patented cyclodextrin technology used in our formulation technology from Janssen Biotech, N.V., or Janssen, and others.

Non-Oncology Proprietary Products

We are currently seeking strategic alliances and licensing agreements for further development of certain non-oncology products, including RF 1010, RF 1051, pyrazinoylguanidine, or PZG and AM 454.

RF 1010 is an analog of a naturally occurring human non-androgenic hormone. We have conducted Phase II trials using RF 1010 to treat various forms of anemia and neutropenia. These diseases destroy red and white blood cells and thereby weaken the immune system, leaving patients susceptible to infections that could result in serious illness or death.

RF 1051, which is a naturally occurring substance in humans, has applications for treatment of diabetes and obesity. Our Phase II trials have indicated that this proprietary oral drug may cause the body to store less fat or use more fat to produce energy. We have received orphan drug designation for RF 1051 in the treatment of Prader-Willi Syndrome, a type of genetic obesity.

PZG is a product for treatment of Type II, or adult-onset, diabetes. Animal studies and early clinical studies of PZG suggest that it may help to control the blood sugar and lipid abnormalities of diabetes, and may have utility in treating a lipid disorder unrelated to diabetes called hypertriglyceridemia, obesity, hypertension and the uremia of renal failure. We initiated a small, well-defined and controlled Phase II study to characterize the hypoglycemic and lipid-lowering effects of PZG in Type II diabetes.

AM 454 is a DHEA phosphocholine derivative which may have utility in obesity and diabetes.

Research and Development

Because of the stage of our development and the nature of our business, we expend significant resources on research and development activities. We expended $26.3 million in 2003, $29.9 million in 2002, and $47.8 million in 2001 on research and development. We conduct research internally and also through collaborations with third parties, and we intend to maintain our strong commitment to our research and development efforts in the future. Our major research and development projects include Orathecin, Dacogen and studies on additional uses for Nipent.

Orathecin

While we believe we have a portfolio of product candidates with promise, we have focused much of our attention and resources on developing Orathecin, and from 1998 through 2003 we have spent approximately $65.0 million on the Orathecin program. In addition, we must establish sales and marketing capability to support the worldwide sale of Orathecin by entering into sales and marketing agreements with collaborators and building up our own sales force, which will involve substantial costs and expenses.

Dacogen

From 1999 through 2003, we have spent approximately $7.9 million on the pre-clinical and clinical development of Dacogen. In multiple Phase II studies in Europe, we believe researchers have preliminarily shown Dacogen to be active in the treatment of MDS. Based on positive results from these studies, we conducted a Phase III study at over 20 leading hospitals in the United States with 170 patients, that compared Dacogen to best supportive care for MDS. This Phase III study was designed to secure regulatory approval for Dacogen in the treatment of MDS. We are currently compiling and validating results from this study.

Nipent

Through December 31, 2003, we have spent approximately $12.5 million on Phase I, II/III, and Phase IV programs related to different indications for Nipent. We believe that Nipent has a unique mechanism of action and Phase IV trials indicate that it may have activity in a variety of other hematologic cancers. We are conducting Phase IV studies for treatment of hematological malignancies and disorders, such as CLL, NHL, and cutaneous and peripheral T-cell lymphomas. Nipent has received orphan drug designation by the FDA for treatment of CLL and cutaneous T-cell lymphoma.

Sales and Marketing

We currently have 34 employees focused on sales, marketing, and sales support of our products to cancer hospitals and clinics in the United States. The large majority of these hospitals are members of hospital buying groups. We have focused our efforts on selling to these groups since they control a significant majority of the business in the oncology and blood disorder pharmaceutical market. We also market our products, including Nipent, to private practice oncology clinics, oncology distributors and drug wholesalers. Oncologists/hematologists, oncology nurses and oncology pharmacists are included in each of these classes of customers.

Since acceptance of our products from each buying group can be time consuming, there may be significant delays before we can win bids and generate sales revenue. To date, a large number of these buying groups, including Premier Purchasing Partners, Novation, Kaiser Permanente, and the Department of Veteran Affairs, have given us approved vendor status for our products. In addition, we have gained recognition as an approved vendor in each state that requires registration or licensing before bidding for those customers.

There are approximately 5,000 private practice oncologists/hematologists in the United States. These physicians usually purchase oncology products through distributors, with whom we have developed relationships. The four major oncology distributors in the United States are Oncology Therapeutic Network Joint Venture, L.P., Florida Infusion Services, Inc., National Specialty Services, Inc. and Priority Healthcare Corporation. These distributors control approximately 60 percent of the private practice oncology clinics, which in turn represent approximately 30 percent of the oncology-related pharmaceutical market. We have taken significant steps in building relationships with these distributors, all of which distribute Nipent. Our sales force will also continue to target the important private practice oncology clinics within their assigned territories. We also sell to large drug wholesalers that supply hospitals and hospital buying groups.

Our sales group is divided into three regions. Each region is headed by a manager with extensive industry experience who supervises specialty oncology sales representatives. We plan to expand our sales force in anticipation of receipt of additional approvals of our products under development. Our sales and marketing group conducts direct sales, sponsors speakers' programs, works with distributors, performs market research analysis, develops marketing strategies, creates and implements educational and promotional programs, establishes pricing and product advertising and maintains compliance with hospital and other buying groups.

Manufacturing

We currently outsource manufacturing for all of our products to United States and foreign suppliers. We expect to continue to outsource manufacturing in the near term. We believe our current suppliers will be able to efficiently manufacture our proprietary and generic compounds in sufficient quantities and on a timely basis, while maintaining product quality and compliance with FDA and foreign regulations. We maintain oversight of the quality control function of our third-party manufacturers through ongoing inspections, rigorous review, control over documented operating procedures, and thorough analytical testing by outside laboratories. We believe that our current strategy of outsourcing manufacturing is cost-effective since we avoid the high fixed costs of plant, equipment, and large manufacturing staffs.

The FDA must issue marketing clearance and deem a manufacturer acceptable under current good manufacturing practices, or GMPs, before production of active pharmaceutical ingredients, finished pharmaceuticals, or proprietary and generic drugs for commercial sale may begin. Once a proprietary or generic compound is manufactured on our behalf, it is sent to one or more domestic manufacturers that process it into the finished dosage forms. We currently follow these procedures for our marketed

products, Nipent and mitomycin. We then ship our finished proprietary and generic products to outside vendors for distribution to our customers.

In December 1997, we received approval from the FDA to commercially manufacture Nipent at one of our designated vendor's manufacturing sites using our proprietary manufacturing process. This vendor declared bankruptcy in July 2001 and closed its manufacturing facility. We transferred the manufacturing of Nipent to a new vendor in mid-2001, and the manufacturer was qualified by the FDA in May 2002. We experienced unusually low inventory levels during the first quarter of 2002, while we were waiting for the new company to be qualified by the FDA. In April 1998, the FDA approved our application for the production and commercial distribution of mitomycin for injection. In November 2001, the FDA approved our application for the production and commercial distribution of daunorubicin hydrochloride injection. See "*Risk Factors—Our business may be harmed if the manufacture of our products is interrupted or discontinued.*"

We intend to continue evaluating our manufacturing requirements and may establish or acquire our own facilities to manufacture our products for commercial distribution if doing so would reduce costs or improve control and flexibility of product supply.

Business Relationships and Material Contracts

Strategic, Collaborative and Licensing Relationships and Related Agreements

We identify and license or buy rights to products or compounds that are typically in human clinical development. We then seek to enhance and complete the product development and bring the product to market internally or through collaborations with others. We have entered into a variety of strategic and collaborative relationships and licensing agreements in pursuing our business. Some of our more significant relationships are as follows:

1. *The Stehlin Foundation for Cancer Research—Orathecin*

In September 1997, we entered into a License Agreement, as subsequently amended in 1999, to license the exclusive worldwide royalty-bearing rights to Orathecin from Stehlin, a Houston, Texas-based cancer research clinic. Under the agreement, we have the right to grant sublicenses, make, import, use, sell, offer for sale and otherwise distribute and exploit the licensed products worldwide, except for Mexico, Canada, Spain, Japan, the United Kingdom, France, Italy and Germany. We must use commercially reasonable efforts to develop the licensed Orathecin products and obtain regulatory approval for the products.

We may, at our sole discretion, enter into agreements with third parties with respect to the development of the licensed products. We must bear our own costs incurred in connection with the development of the products, and, except for the payments described in the agreement, Stehlin will bear its own costs incurred in connection with the performance of the research activities that we may request and Stehlin agrees to undertake in connection with the development of the licensed products. The development responsibilities under the agreement are coordinated by a committee consisting of an equal number of employees of each party, provided that we have the deciding vote in the event of any disagreement.

Stehlin continues to hold the title to all inventions and other intellectual property made solely by employees or consultants of Stehlin with respect to Orathecin, and we hold the title to all inventions and other intellectual property made solely by our employees or consultants in connection with activities under the agreement. Title to all inventions and other intellectual property made jointly by employees or consultants of the parties in connection with the agreement are jointly owned by the parties. In the event Stehlin elects to license any product (other than the Orathecin products) for human medicinal purposes for any uses that include pancreatic cancer or antineoplastic use, we have

the right of first refusal to obtain from Stehlin a license under patents owned or controlled by Stehlin to market such products.

We were required to pay Stehlin approximately $9.6 million for research. Our agreement with Stehlin also calls for additional payments in our common stock upon the achievement of specified milestones and royalties on any product sales. We must make milestone payments under the agreement upon (a) notification by the FDA of the acceptance for filing of the first NDA submitted for Orathecin and (b) our receipt of the FDA notice that it has approved Orathecin for marketing. Each of such payments will be made in restricted shares of our common stock at a per share purchase price equal to the average trading price of the shares over a 30-day trading period. Through December 31, 2003, we have paid Stehlin all of the $9.6 million required for research, but have not yet paid any milestone or royalty payments.

Unless terminated sooner as provided in the agreement, the agreement will continue in full force and effect on a country-by-country and licensed product-by-licensed product basis until there are no remaining royalty payment obligations in a country, at which time the agreement will terminate in its entirety in such country. We will continue to have a perpetual, non-exclusive, royalty-free license, with the right to grant sublicenses, to make, import, use, sell, offer for sale and otherwise distribute and exploit the Orathecin products for human medicinal purposes in such country. We may terminate the agreement with respect to any country with 60 days written notice to Stehlin. In addition, if either party materially breaches the agreement, the other party will have certain termination rights. Further, either party may terminate the agreement if the other becomes the subject of a voluntary or involuntary petition in bankruptcy or any proceeding relating to insolvency, receivership or liquidation for the benefit of creditors, if that petition or proceeding is not dismissed with prejudice within 60 days after filing.

2. *Pharmachemie—Dacogen*

In September 1999, we entered into a Know-How Transfer and Cooperation Agreement with Pharmachemie. Under the agreement, Pharmachemie sold and transferred to us its know-how related to a pharmaceutical product approach for the treatment of leukemia and other hematologic malignancies, called the "Decitabine Project." Under the agreement, we obtained all rights and title with respect to the know-how related to the Decitabine Project, including the related intellectual property rights, such as patent applications, and the exclusive world-wide right to use the know-how for any purpose whatsoever, including the filing of applications for marketing approval of the products. Upon execution of the agreement, we delivered to Pharmachemie shares of our common stock equal to $3.4 million aggregate amount.

3. *Warner-Lambert Company (Pfizer)—Nipent*

In September 1996, we entered into a Purchase and Sale Agreement with the Warner-Lambert Company (Pfizer), pursuant to which we agreed to purchase the exclusive rights to the anti-cancer drug Nipent from Warner-Lambert for the United States, Canada and Mexico. The assets we acquired included all of Warner-Lambert's unpurified crude concentrate form of pentostatin, from which Nipent is made, and related inventory, new drug application, Canadian new drug submission and certain intellectual property.

Under the agreement, we granted Warner-Lambert an irrevocable, non-exclusive, worldwide, perpetual and royalty-free license to use the know-how acquired by us under the agreement (in or outside the territories of the United States, Canada and Mexico) to the extent necessary to manufacture the pentostatin product for sale exclusively outside the United States, Canada and Mexico. Warner-Lambert may sublicense or assign such rights to any third party, subject to the terms of the agreement.

In addition, to the extent not acquired by us under the agreement, Warner-Lambert granted us an irrevocable, non-exclusive, worldwide, perpetual and royalty-free license to use all the technical know-how reasonably required or useful for the manufacture of the pentostatin products under the agreement, and any other intellectual property owned or licensed by Warner-Lambert as of the closing date necessary or helpful in the manufacture of the pentostatin products.

In consideration for the assets and related intellectual property rights acquired by us under the agreement, we paid Warner-Lambert $2.1 million in cash and $1.0 million in unregistered shares of our common stock, followed by an additional cash payment of $500,000.

We have recently entered into an agreement with Pfizer to acquire the distribution and marketing rights to Nipent in Europe.

4. *Peregrine Pharmaceuticals—VEGF*

In February 2001, we entered into a License Agreement to license a platform drug-targeting technology known as Vascular Targeting Agent from Peregrine Pharmaceuticals. The licensed technology is related to Vascular Endothelial Growth Factor. The VTA technology is a proprietary platform designed to specifically target a tumor's blood supply and subsequently destroy the tumor with various attached therapeutic agents.

Under the agreement, we obtained an exclusive, worldwide, royalty-bearing license to Peregrine's patents related to the VEGF technology, which permits us to make, use, import, sell and otherwise exploit and distribute licensed products using the VEGF technology. We may also grant sublicenses under the agreement.

The agreement required an up-front payment of $600,000, which included the acquisition of 150,000 shares of Peregrine common stock valued at $253,000. The remaining $347,000 of the payment was recorded to research and development expense. We are also required to pay Peregrine an annual license fee of $200,000 per year in cash or our common stock until the first filing of an investigational new drug application, or IND, in the United States utilizing the licensed patents. In addition, the terms of the agreement require that we pay milestone payments and royalties to Peregrine based on the net revenues of any drugs commercialized using the VEGF technology. The milestone payments could ultimately total approximately $8.25 million, plus additional royalty payments as required under the agreement. We are required to make milestone payments to Peregrine upon (a) commencement by us of the first Phase III trial in the United States, Europe or Japan for the first therapeutic clinical candidate covered under the licensed patents; (b) commencement by us of Phase III trial in the United States, Europe or Japan for subsequent therapeutic clinical candidates covered under the licensed patents; (c) commencement by us of a Phase II/III trial, if any; (d) receipt of regulatory approval in the United States for the first therapeutic clinical candidate covered under the licensed patents; (e) receipt of regulatory approval in a European nation for the first therapeutic clinical candidate covered under the licensed patents; and (f) receipt of regulatory approval in Japan for the first therapeutic clinical candidate covered under the licensed patents.

The agreement will continue in full force and effect on a country-by-country and licensed product-by-licensed product basis until there are no remaining royalty payment obligations in a country, at which time the agreement will terminate in its entirety in such country, unless terminated sooner as provided in the agreement. Upon termination of the agreement in any country, we will have a non-exclusive, irrevocable, fully paid-up right and license to use and exploit the licensed patents in that country. We may terminate the agreement with respect to any country with 30 days written notice to Peregrine. In addition, if either party materially breaches the agreement, the other party will have termination rights.

5. *AMUR Pharmaceuticals, Inc.*

In September 2000, we acquired the intellectual property of AMUR Pharmaceuticals, Inc., or AMUR, a company with the proprietary rights to AM 454, which can potentially prevent the onset of Type II diabetes according to pre-clinical animal studies, and rights to a 20K growth hormone, with potential for treatment of Type II diabetes. AMUR's technology is based on a water-soluble class of hormones. We acquired these rights in exchange for 37,795 shares of our common stock and two-year warrants to purchase 200,000 shares of our common stock at $40.00 per share. In 2002, these warrants were extended for two additional years. Two of our current directors and two of our former directors were formerly directors of AMUR. The president of AMUR performed consulting services for us and was paid $15,000 in 2003, $180,000 in 2002, and $180,000 in 2001 for these consulting services. In addition, in September 1999 this individual was granted an option to purchase 5,000 shares of our stock.

6. *Clayton Foundation for Research—Camptothecin and Paclitaxel*

Research Agreements

In November 1999, we entered into two research agreements with the Clayton Foundation for Research, or Clayton, a Texas nonprofit corporation, and the Research Development Foundation, or RDF, a Nevada nonprofit corporation, to provide funding to Clayton for use in its research involving cancer therapy and camptothecin under one agreement and cancer therapy and paclitaxel under the second agreement. RDF is affiliated with Clayton and is assigned title to inventions, discoveries and know-how arising out of Clayton's research for patenting and licensing. As set forth in the related license agreements, we obtained exclusive licenses from RDF to any inventions or discoveries arising out of the research funded under the research agreements. Clayton has ongoing research involving cancer therapy, including research regarding each of camptothecin and paclitaxel under the direction of Vernon Knight, M.D., at Baylor College of Medicine in Texas. The paclitaxel research agreement expired by its terms in November 2001, and the camptothecin agreement, which was extended to the end of 2002 in May 2002, also expired.

License Agreements

In November 1999, we entered into two license agreements with RDF to obtain exclusive, worldwide licenses from RDF to produce, make, manufacture, use, sell, rent and lease methods, processes or products involving RDF's camptothecin product and RDF's paclitaxel product, and related proprietary property under the agreements. We have agreed to use commercially reasonable efforts with regard to commercialization of the products under the agreements.

Under the terms of the agreements, RDF may not license any other party rights to deliver camptothecin or paclitaxel, or analogues thereof, alone or in combination with another drug, in liposomes, lipid complexes or other liposome particles to the respiratory tract via aerosol droplets. We also have the right to grant sublicenses to others within the scope of and under the terms and conditions of the agreements. We must provide written notice of any such sublicenses to RDF. We also have the right to review and reference the know-how in any application or filing relating to the proprietary property with any governmental or regulatory authority.

RDF will, at its own expense, file patent applications relating to the proprietary property in the United States and any other countries agreed upon by the parties under the agreements. RDF agrees to use its best efforts to prosecute such patent applications and to maintain any patents issued thereon. We, in our sole discretion, may elect to assume responsibility (and to pay any associated fees and expenses) with respect to any patent applications or patents that RDF intends to abandon. We may abandon any patent applications or patents for which we have assumed responsibility and will not be liable to RDF in any way for such abandonment.

Any improvements on the proprietary property under the agreements, whether patentable, copyrightable or not, now or hereafter made and found by our agents or employees, shall be owned by RDF and will be considered part of the licensed proprietary property under the agreements. The worldwide rights in the corresponding patents, patent applications, copyrights and/or know-how will be the property of RDF subject to all the terms and conditions of the agreements, and will be licensed to us under the applicable agreement.

Upon execution of each of the agreements, we paid RDF an up-front non-refundable license fee consisting of $410,000 in shares of our common stock under each agreement. In addition, we must pay RDF royalties based on gross revenues under the agreements. Only one royalty will be payable on a product, regardless of the number of licensed applications and licensed patents of the proprietary property under which such product has been manufactured, used or sold. We will also pay RDF fees received from sublicensees of the licensed proprietary property under the agreements. However, the parties agree that RDF is not entitled to any share of amounts received by us for pilot studies, research and development, the license or sublicense of any intellectual property other than the licensed proprietary property, reimbursement for patent or other expenses, or as consideration for equity or debt in connection with activities under the agreement.

In addition to the up-front license fee and royalties, we must also make milestone payments to RDF in the form of our common stock with respect to each product under the agreements upon (a) the earlier of (1) approval or (2) the date of effectiveness of an investigational new drug application, or IND, filed with the FDA for such product; (b) completion of a Phase I human clinical trial for such product and the final report thereon; (c) completion of a Phase II human clinical trial for such product and the final report thereon; (d) completion of any other phase of human clinical trials for such product required by the FDA and the final report thereon; and (e) upon approval by the FDA of an NDA for such product.

The term of each of the agreements is for a period of ten years extending from the first commercial revenue actually collected under the applicable agreement or for the life of the last to expire of the patents or patent applications of the licensed proprietary property thereunder, whichever is earlier, unless sooner terminated by the parties pursuant to the applicable agreement.

7. *Cyclex, Inc.*

In March 1994, we entered into a Patent License Agreement with Cyclex, Inc. pursuant to which we obtained a license under a patent identified in the agreement to make, use and sell pharmaceutical products for cytotoxic anti-cancer formulations containing HPBCD and certain other ingredients, for use in the United States. Cyclex agrees that it will not enter into a license agreement with any other parties granting the rights to make, use and sell the licensed products in the United States. The rights granted to us under the agreement are non-transferable, and we may not grant sublicenses thereof.

In consideration of the rights granted under the agreement, we must pay a three percent royalty to Cyclex on our net sales under the agreement. Only one royalty payment is due to Cyclex for the initial sale made by us or for the internal transfer price of each licensed product. The agreement will remain in effect until the expiration of the licensed patent under the agreement, or a final finding of invalidity or withdrawal of the licensed patent, subject to earlier termination for breach.

8. *Janssen Biotech, N.V.*

In March 1994, we entered into a Worldwide License Agreement with Janssen, pursuant to which we obtained from Janssen an exclusive license to make, use and sell the pharmaceutical cytotoxic anti-cancer formulations containing HPBCD and certain other ingredients as developed by Janssen, for use worldwide except in the United States. We also have the right to grant sublicenses of the product. The rights granted under the agreement are otherwise non-transferable, except to affiliates.

In consideration of the rights granted under the agreement, we must pay a royalty of four percent for the license of the know-how in all countries and a royalty under the patent rights of three percent in those countries where patent rights have been granted. In addition, we paid Janssen a down payment of $60,000 in connection with the execution of the agreement, and must make additional milestone payments to Janssen during the term of the agreement. We paid $350,000 in 2003 following the approval of Mitozytrex.

The agreement will remain in effect until the expiration of the last to expire patent rights under the agreement, subject to earlier termination for breach. In the event, however, that after the expiration of the patent rights the know-how under the agreement is still confidential and substantial, then the term of the agreement will be renewed for successive periods of one year each during which our obligations to pay royalties under the agreement will be limited to know-how related royalties.

9. *The Jackson Laboratory*

In September 1993, we entered into a Patent License and Royalty Agreement with The Jackson Laboratory, or Jackson, pursuant to which we obtained an exclusive right and license in and to the patents and patent rights related to three patents identified in the agreement, which relate to our proprietary formulation technology, together with the right to grant sublicenses thereof. Jackson retained a royalty-free, non-exclusive, non-transferable license and right to the patent rights under the agreement for its own research and institutional purposes. We have the right to state in any advertising, promotions or sales materials that we are the exclusive licensee of Jackson under the patents covered by the agreement.

Upon execution of the agreement, we paid Jackson a one-time reimbursement fee of $25,000. In addition, we must pay Jackson royalties equal to two percent of the net sales price of any patent products leased or sold by us, and a royalty equal to ten percent of the net royalty paid to us on account of any lease or sale of such patent rights and related products. We must also pay Jackson an annual payment of $2,500 per year, payable each year until the year of the last-to-expire patent rights. We must also pay any expenses for the preparation and filing of new patent applications and patent maintenance fees for all issued patents covered by the agreement.

The agreement may be terminated by Jackson if we cease to carry on our business, fail to pay royalties owed under the agreement or otherwise materially breach the agreement. We may terminate the agreement upon six month's notice to Jackson.

10. *AVI BioPharma, Inc.—Avicine*

In December 1999, we entered into an agreement with AVI to acquire one million shares of AVI common stock, which amounted to approximately 7.5 percent of AVI's then outstanding common stock, for $2.5 million cash and 100,000 shares of our common stock at $28.25 per share. The chief executive officer of AVI at the time was a member of our board of directors (who later resigned from our board in May 2002), and one of the members of our board of directors is a member of the board of directors of AVI. We also acquired exclusive negotiating rights for the United States market for Avicine, AVI's proprietary cancer vaccine currently in late-stage clinical testing against a variety of solid tumors. Avicine is an immunotherapy that neutralizes the effect of a tumor-associated antigen on cancer cells, while stimulating the body's immune system to react against the foreign tumor.

In April 2000, we entered into a United States sales, distribution and development agreement with AVI to become the exclusive distributor and promoter in the United States of any pharmaceutical product containing Avicine.

Under the terms of the agreement, we are responsible for advertising, marketing, selling and promoting Avicine in the United States, and AVI is responsible for product manufacturing, packaging,

sterilization and labeling. AVI has granted us an exclusive license to sell the Avicine products in the United States. In the event that AVI or its third-party manufacturers are unable to fill product orders for a total of 60 days, then we will have a non-exclusive license to manufacture Avicine products. If AVI is unable to meet its obligations under the agreement for six months, AVI must notify us and the parties will consider steps to preserve our rights to Avicine, including, but not limited to, the grant of a non-exclusive, royalty bearing license to us to develop and sell Avicine products in the United States. Under the agreement, we also obtained the right of first discussion with respect to all of AVI's oncology compounds.

We formed a joint Clinical Development Committee with AVI to oversee, review and coordinate the implementation of the clinical studies and the pursuit of regulatory approvals in the United States, and we will equally share the costs for the FDA approval process. In addition, any net profits from the sale of Avicine products in the United States will be split equally among the parties. Further, the parties will jointly determine the optimum development strategy for the international marketplace.

AVI will maintain any patents owned by it or licensed to AVI relating to Avicine as identified and agreed to by the parties, and AVI will use its reasonable commercial efforts to prosecute any agreed upon patent applications. In addition, the parties will consult together and jointly determine patent issues, including patenting strategy, prosecution and response to patent office actions. AVI will be solely responsible for the selection, filing, registration and maintenance of any AVI trademarks related to Avicine in the United States. We have a non-exclusive limited license to use AVI's name and logo in the United States, and a co-exclusive limited license to use AVI trademarks related to Avicine in the United States, in each instance solely for the purpose of promoting, distributing and selling Avicine products in the United States in accordance with the terms and conditions of the agreement.

In consideration of past research and development performed by AVI, we made an additional equity investment in AVI totaling $22.0 million in exchange for 1,684,211 shares of AVI common stock, paid in a combination of $5.0 million cash and the issuance of 347,826 shares of our common stock. As part of the agreement, we have a warrant to acquire up to an additional ten percent of AVI's common stock at an aggregate exercise price equal to $60.0 million, or $35.625 per share. This warrant is exercisable for a three-year period commencing on the earlier of the date the FDA accepts the NDA submitted for Avicine, or the date on which the closing price of AVI's common stock exceeds the warrant exercise price. Neither event has occurred as of December 31, 2003.

We will be required to make additional milestone payments to AVI for an aggregate of up to $80.0 million, including (a) $2.5 million in our stock or cash, upon completion of accrual into the Phase III trial for Avicine; (b) $2.5 million in our stock or cash, upon acceptance by the FDA of the NDA submitted for Avicine; (c) $5.0 million in our stock or cash, upon launch of Avicine in the United States, (d) $10.0 million in cash, when our annual Avicine product sales reach $100.0 million; (e) $15.0 million in cash, when our annual Avicine product sales reach $250.0 million; (f) $20.0 million in cash, when our annual Avicine product sales reach $500.0 million; and (g) $25.0 million in cash, when our annual Avicine product sales reach $1.0 billion. The ability to make milestone payments in our stock shall be at our option, subject to ownership limitations.

Unless terminated sooner as provided in the agreement, the agreement will expire upon the earlier of (a) the date upon which a generic version of Avicine is first sold in the United States by someone other than us or (b) the date which is 15 years after the date of regulatory approval of Avicine in the United States, provided that the we and AVI may renew the agreement for the United States for (1) further successive one year periods, or (2) further successive periods of time during which any applicable marketing exclusivity precludes the effective approval by the FDA of any product containing Avicine. In addition, either party may terminate the agreement if the ownership or control of at least 50 percent of the assets or voting securities of the other party are transferred and, in the non-changing

party's reasonable judgment, the other party's new owner or controlling entity is a competitor of the non-changing party in the field of oncology.

Supply and Distribution Agreements

We have entered into a variety of supply and distribution agreements in pursuing our business. Some of our more significant relationships are as follows:

1. *Abbott Laboratories—Nipent*

In December 1999, we entered into a Nipent U.S. Distribution Agreement with Abbott Laboratories. Under the agreement, we must supply Nipent inventory exclusively to Abbott on a consignment basis, for distribution by Abbott within the United States. At no time during the performance of the agreement will title to the products pass from us to Abbott.

As of March 1, 2000, Abbott became the exclusive United States distributor of Nipent for a period of five years under the agreement, with the sole and exclusive right to commercially distribute the product to third parties within the United States. Abbott may sell and distribute Nipent in the United States, collect monies due for those sales, convey a portion of such monies to us four times per year, and retain a portion of the monies collected as the fee for the distribution work. We retain all United States promotional, advertising and marketing rights for Nipent. Upon receipt by Abbott of orders for products under the agreement, Abbott must ship and invoice the products at the wholesale acquisition cost for the product established by us and reported to Abbott.

In January 2000, Abbott made a $5.0 million cash payment to us in connection with the granting of the exclusive distribution rights by us to Abbott. In March 2003, we paid Abbott $500,000 for the right to terminate the agreement at our option, for a stated fee that decreases over time to $1.5 million at March 2005.

2. *Warner-Lambert Company (Pfizer)—Nipent*

In October 1997, we entered into a Supply Agreement with Warner-Lambert Company (Pfizer), pursuant to which we contracted to manufacture and supply the pharmaceutical preparation for human use containing pentostatin in unlabeled sterile filled vials to Warner-Lambert or any entity designated by Warner-Lambert to act on its behalf with respect to the purchase of the product, for sale outside of North America (United States, Canada and Mexico) and Japan.

Under the agreement, we agreed to supply the pentostatin product to Warner-Lambert for sale outside of North America and Japan, and Warner-Lambert agreed to buy its total requirements of the pentostatin product for sale in the designated territories from us or our designee. Title to the products sold to Warner-Lambert or its designee under the agreement and risk of loss will pass to Warner-Lambert or its designee when the products are presented for customs clearance of the country of the designated designation. Warner-Lambert also agreed that: (1) all of the product purchased under the agreement will be purchased for resale or otherwise distributed solely in the designated territory and (2) none of the products purchased under the agreement will be resold or otherwise distributed in the United States, Canada or Mexico.

In addition, the agreement contains non-compete obligations whereby Warner-Lambert agrees that it will not, for the longer of (1) the term of the agreement and thereafter for a period of three years or (2) a period of ten years from the date of the agreement, directly or indirectly, sell pentostatin anywhere in the United States, the Commonwealth of Puerto Rico, Canada or Mexico or have any ownership interest in, or participate in the financing, operation, management or control of any person selling pentostatin in such areas. With respect to regulatory requirements regarding the pentostatin products supplied under the agreement, we are responsible for obtaining and maintaining all

registrations required by any governmental or regulatory authority of the United States and Warner-Lambert is responsible for obtaining and maintaining all registrations required by any governmental or regulatory authority of any country in the designated territories.

The agreement will remain in effect for seven years following the day on which we or our designee makes the first delivery of the product to Warner-Lambert or Warner-Lambert's designee, subject to earlier termination by either party for breach.

We have recently entered into an agreement with Pfizer to acquire the distribution and marketing rights to Nipent in Europe.

3. *Hauser Technical Services—Pentostatin (Nipent)*

In December 2002, we entered into a Pentostatin Supply Agreement with Hauser Technical Services, Inc., or Hauser. Under the agreement, Hauser will batch-process pentostatin crude concentrate supplied to Hauser by us or parties authorized by us, to yield pentostatin as an active pharmaceutical ingredient, or API. Hauser must notify us before it may subcontract any part of its responsibilities under the agreement to another party.

Prior to processing each batch of pentostatin crude concentrate under the agreement, we must furnish Hauser (at no cost to Hauser) a sufficient amount of pentostatin crude concentrate. Hauser is not required to store pentostatin crude concentrate for a certain number of batches. The agreement requires Hauser to provide us with the batch records, copies of raw data, all calculated data, exception reports and other documents approved by Hauser for review prior to shipping any deliverables under the agreement pursuant to our instructions. Hauser must pay the costs of the raw materials (except the pentostatin crude concentrate) used under the agreement.

Hauser agrees to reserve one of its facilities for use pursuant to the agreement. In the event that we do not order certain batches of pentostatin crude concentrate for processing in any contract year during the term of the agreement, we agree to pay Hauser a shortfall payment following the end of such contract year. We must provide Hauser with written forecasts in January and June of each contract year regarding the number of batches of pentostatin crude concentrate that we expect to require Hauser to process over the subsequent 12-month period. In addition, we are solely responsible for applying for, obtaining and paying the costs regarding any approvals from regulatory authorities relating to the registration of the API, and we will own any new drug application supplement in connection therewith. Hauser agrees to reasonably cooperate and assist us in obtaining such approvals.

Under the agreement, we have title to all pentostatin crude concentrate, all work-in-process, all API and deliverables processed for us (including stability samples), standards for pentostatin and the s-isomer standards subject to the agreement. If any damage or loss of the pentostatin crude concentrate occurs prior to the time that Hauser completes the processing of the API, and such damage or loss is the result of Hauser's mishandling of the pentostatin crude concentrate (whether by negligence or breach of its obligations under the agreement), then Hauser will credit us on the next invoice or otherwise reimburse us for the cost of any labor and raw materials paid for by us that were used, damaged or lost. In addition, Hauser would need to pay us a mitigation fee in connection with such loss or damage.

The initial term of the agreement will be for a period of two years from execution. The parties may agree in writing to renew the agreement for additional one-year periods. The agreement may be terminated (1) upon mutual written consent of the parties, (2) by us upon 30-days written notice to Hauser for any reason or no reason, (3) by either party in the event of a material breach, insolvency or bankruptcy of the other party, or a force majeure event that continues for at least 60 days following notice by the other party, (4) by Hauser upon 12-months written notice to us if Hauser or its successors choose to move to a new processing facility or (5) by Hauser if we do not approve increases to the

processing fees under the agreement due to cost increases for the material safety data sheets for the finished API and raw materials. If the agreement is terminated pursuant to clause (2) or (5) of the preceding sentence, then we will need to reimburse Hauser for the cost of any unique unused raw materials and pay Hauser a termination fee.

Hauser Inc., Hauser's parent company, and its wholly-owned subsidiaries filed for reorganization under chapter 11 in April 2003. However, we do not believe that this filing will have any significant impact on our supply agreement and our ability to process pentostatin, although there can be no assurance in this regard.

4. *EuroGen Pharmaceuticals Ltd.*

In September 2001, we entered into a Supply and Distribution Agreement with EuroGen. Under the agreement, we granted EuroGen the exclusive European and South African rights to promote, market, distribute and sell certain of our existing generic and other products or compounds. The agreement also establishes a process for granting EuroGen rights to sell additional products in Europe and South Africa, subject to our compliance with our other existing licensing and distribution arrangements. After complying with these existing obligations, which include giving certain third parties a right of first discussion, we will be required to offer EuroGen the option to obtain European and South African rights to certain of our other products. The agreement grants EuroGen a non-exclusive limited license to use our name and logo in connection with activities under the agreement. EuroGen is required to seek and pay for all regulatory approvals and authorizations necessary for the commercial sale of the products in the territories where they market and sell the products.

The term of the agreement will expire 15 years after the date of regulatory approval of the product under the agreement in the first country within the designated territory, unless terminated sooner for breach, bankruptcy or insolvency of one of the parties. In addition, we may terminate the agreement if EuroGen directly or indirectly develops, markets, sells or otherwise distributes any products within the designated territory, which could compete with the products under the agreement, or EuroGen appoints any third party to develop, market, sell or otherwise distribute any such products which could compete with the products under the agreement.

During 2001, we loaned EuroGen $260,000 under a line of credit arrangement designed to cover start-up expenses. During 2002, we advanced an additional $646,000 to EuroGen to fund its operations. In December 2002, all but one of the other investors in EuroGen withdrew their ownership interests in the entity, and we became 95 percent owners of EuroGen. The remaining five percent is owned by Larry Johnson, the President and CEO of EuroGen. The amounts advanced to EuroGen, including the amounts advanced in 2001, totaling $906,000 were charged to Selling, general, and administrative expense in 2002. In 2003 we have included the results of EuroGen in our consolidated operations as they are a subsidiary, and accordingly, $325,000 has been charged to Selling, general, and administrative expense.

5. *Yunnan Hande Technological Development Co. Ltd.—Paclitaxel*

In May 1997, we entered into a Non-Exclusive Supply Agreement with Yunnan Hande Technological Development Co. Ltd., or Yunnan. Yunnan has developed a process for the production of paclitaxel and has sought to implement a process that meets current GMPs, and we have consulted with Yunnan regarding the development plans for the production of Paclitaxel and other products.

Under the agreement, we agreed to purchase a minimum quantity of paclitaxel before the end of one year from the date of approval of our ANDA for the paclitaxel drug product, on a non-exclusive basis. Yunnan is free to sell paclitaxel to any party in any place and we are free to purchase paclitaxel from third parties. We must pay Yunnan an aggregate of $1.0 million during the FDA inspection period for the products.

Government Regulation: New Drug Development and Approval Process

Regulation by governmental authorities in the United States and other countries is a significant factor in the manufacture and marketing of pharmaceuticals and in our ongoing research and development activities. All of our drug products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous pre-clinical testing, clinical trials and other pre-marketing approval requirements by the FDA and regulatory authorities in other countries. In the United States, various federal, and in some cases state statutes and regulations also govern or impact upon the manufacturing, safety, labeling, storage, record-keeping and marketing of such products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations, require the expenditure of substantial resources. Regulatory approval, when and if obtained, may be limited in scope which may significantly limit the indicated uses for which a product may be marketed. Further, approved drugs, as well as their manufacturers, are subject to ongoing review and discovery of previously unknown problems with such products, which may result in restrictions on their manufacture, sale or use or in their withdrawal from the market.

The process for new drug approval has many steps, including:

Drug discovery. In the initial stages of drug discovery before a compound reaches the laboratory, tens of thousands of potential compounds are randomly screened for activity against an assay assumed to be predictive for particular disease targets. This drug discovery process can take several years. Once a company locates a "screening lead," or starting point for drug development, isolation and structural determination may begin. The development process results in numerous chemical modifications to the screening lead in an attempt to improve the drug properties of the lead. After a compound emerges from this process, the next steps are to conduct further preliminary studies on the mechanism of action, further in vitro, or test tube, screening against particular disease targets and finally, some in vivo, or animal, screening. If the compound passes these barriers, the toxic effects of the compound are analyzed by performing preliminary exploratory animal toxicology. If the results demonstrate acceptable levels of toxicity, the compound emerges from the basic research mode and moves into the pre-clinical phase.

Pre-clinical testing. During the pre-clinical testing stage, laboratory and animal studies are conducted to show biological activity of the compound against the targeted disease, and the compound is evaluated for safety. These tests typically take approximately three and one-half years to complete, and must be conducted in compliance with Good Laboratory Practice regulations.

Investigational new drug application. During the pre-clinical testing, an IND is filed with the FDA to begin human testing of the drug. The IND becomes effective if not rejected by the FDA within 30 days. The IND must indicate the results of previous experiments, how, where and by whom the new studies will be conducted, the chemical structure of the compound, the method by which it is believed to work in the human body, any toxic effects of the compound found in the animal studies and how the compound is manufactured. All clinical trials must be conducted in accordance with good clinical practices, or GCPs. In addition, an Institutional Review Board, or IRB, comprised of physicians at the hospital or clinic where the proposed studies will be conducted, must review and approve the protocol. The IRB also continues to monitor the study for any safety issues. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. In addition, the FDA may, at any time during the 30-day period or at any time thereafter, impose a clinical hold on proposed or ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. In some instances, the IND application process can result in substantial delay and expense.

Some limited human clinical testing may be done under a "Physician's IND" in support of an IND and independent of a company-filed IND. A Physician's IND is an IND that allows a lone individual to conduct a clinical trial. A Physician's IND does not replace the more formal IND process, but can provide a preliminary indication as to whether further clinical trials are warranted, and can, on occasion, facilitate the more formal IND process.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap.

Phase I clinical trials. After an IND becomes effective, Phase I human clinical trials can begin. These tests, involving usually between 20 and 80 healthy volunteers or patients, typically take approximately one year to complete. The tests study a drug's safety profile, and may include the safe dosage range. The Phase I clinical studies also determine how a drug is absorbed, distributed, metabolized and excreted by the body, and the duration of its action. Phase I/II trials are normally conducted for anti-cancer product candidates.

Phase II clinical trials. In Phase II clinical trials, controlled studies are conducted on approximately 100 to 300 volunteer patients with the targeted disease. The primary purpose of these tests is to evaluate the effectiveness of the drug on the volunteer patients as well as to determine if there are any side effects. These studies generally take approximately two years, and may be conducted concurrently with Phase I clinical trials. In addition, Phase I/II clinical trials may be conducted to evaluate not only the efficacy of the drug on the patient population, but also its safety.

Phase III clinical trials. This phase typically lasts about three years and usually involves 1,000 to 3,000 patients. During the Phase III clinical trials, physicians record observations as defined in the sponsor's protocol onto "case report" forms. These data are monitored regularly by company clinical monitors as well as the participating physician. There are specific requirements for the physician to report any adverse reactions that may result from the use of the drug. Company clinical monitors visit the sites regularly and transmit the data back to the company for analysis and ultimately for presentation to the FDA.

New drug application. After the completion of the clinical trial phase, and with considerable interaction with the FDA, a company prepares an NDA for submission to the FDA. The NDA must contain all of the information on the drug gathered to that date, including data from the clinical trials. NDAs are often over 100,000 pages in length.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. In such an event, the NDA must be resubmitted with the additional information and is again subject to review before filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Federal Food, Drug and Cosmetic Act, the FDA has specified time frames in which to review the NDA and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification regarding information already provided in the submission. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. If FDA evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. If the FDA's evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or issue a not approvable letter.

Marketing approval. If the FDA approves the NDA, the drug becomes available for physicians to prescribe. Periodic reports must be submitted to the FDA, including descriptions of any adverse reactions reported. The FDA may request additional studies (Phase IV) to evaluate long-term effects.

Phase IV clinical trials and post marketing studies. In addition to studies requested by the FDA after approval, these trials and studies are conducted to explore new indications. The purpose of these trials and studies and related publications is to broaden the application and use of the drug and its acceptance in the medical community.

"Fast Track." A fast track product is defined as a new drug or biologic intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for such a condition. Under the fast track program, the sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a fast track product at any time during the clinical development of the product. The FDA Modernization Act of 1997 specifies that the FDA must determine if the product qualifies for fast track designation within 60 days of receipt of the sponsor's request. If a preliminary review of the clinical data suggests efficacy, the FDA may initiate review of sections of an application for a fast track product before the application is complete on a timetable agreeable to the FDA. This "rolling" review is available if the applicant provides a schedule for submission of remaining information and pays applicable user fees.

We obtained fast track designation for Orathecin for the treatment of patients with locally advanced or metastatic pancreatic cancer, and Dacogen for MDS, and intend to seek such designation for other appropriate products. We cannot predict the ultimate impact, if any, of the fast track process on the timing or likelihood of FDA approval of any of our potential products. See "*Risk Factors—Neither the fast track designations of Orathecin and Dacogen nor the accelerated approval procedures for Orathecin will necessarily lead to a faster regulatory review or approval.*"

Approvals in European Union. In 1993, the EU established a system for the registration of medicinal products in the EU and under the system, marketing authorization may be submitted at either a centralized or decentralized level. The centralized procedure is administered by the European Agency for the Evaluation of Medicinal Products. This procedure is mandatory for the approval of biotechnology products and is available at the applicant's option for other innovative products. The centralized procedure provides, for the first time in the EU, for the granting of a single marketing authorization that is valid in all EU member states. A mutual recognition procedure is available at the request of the applicant for all medicinal products that are not subject to the mandatory centralized procedure, under a decentralized procedure. The decentralized procedure creates a new system for mutual recognition of national approvals and establishes procedures for coordinated EU action on product suspensions and withdrawals. Under this procedure, the holder of a national marketing authorization for which mutual recognition is sought may submit an application to one or more member states, certifying that identical dossiers are being submitted to all member states for which recognition is sought. Within 90 days of receiving the application and assessment report, each member state must decide whether or not to recognize the approval. The procedure encourages member states to work with applicants and other regulatory authorities to resolve disputes concerning mutual recognition. If such disputes cannot be resolved within the 90-day period provided for review, the application will be subject to a binding arbitration procedure at the request of the applicant. Alternatively, the application may be withdrawn.

We have applied, through EuroGen, for regulatory approval to market mitomycin and paclitaxel in the United Kingdom and in certain other countries within the EU. We intend to make a centralized filing for regulatory approval for Orathecin in the EU. Our product candidates will be regulated in Europe as medicinal products.

Approvals outside of the United States and EU. Steps similar to those in the United States must be undertaken in virtually every other country comprising the market for our products before any such product can be commercialized in those countries. The approval procedure and the time required for approval vary from country to country and may involve additional testing. There can be no assurance that approvals will be granted on a timely basis or at all. In addition, regulatory approval of prices is required in most countries other than the United States. There can be no assurance that the resulting prices would be sufficient to generate an acceptable return to us.

Off-Label Use. Physicians may prescribe drugs for uses that are not described in the product's labeling for uses that differ from those tested by us and approved by the FDA. Such "off-label" uses are common across medical specialties and may constitute the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use. Companies cannot actively promote FDA-approved drugs for off-label uses, but they may disseminate to physicians articles published in peer-reviewed journals, like *The New England Journal of Medicine*, that discuss off-label uses of approved products. To the extent allowed by law, we intend to disseminate peer-reviewed articles on our products to our physician customers. If, however, our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA.

Generic drug development

For certain drugs that are generic versions of previously approved products, there is an abbreviated FDA approval process. A sponsor may submit an ANDA for:

- a drug product that is the "same" as the drug product listed in the approved drug product list published by the FDA (the "listed drug") with respect to active ingredient(s), route of administration, dosage form, strength and conditions of use recommended in the labeling;
- a drug product that differs with regard to certain changes from a listed drug if the FDA has approved a petition from a prospective applicant permitting the submission of an ANDA for the changed product; and
- a drug that is a duplicate of, or meets the monograph for, an approved antibiotic drug.

An ANDA need not contain the clinical and pre-clinical data supporting the safety and effectiveness of the product. The applicant must instead demonstrate that the product is bioequivalent to the listed drug. FDA regulations define bioequivalence as the absence of a significant difference in the rate and the extent to which the active ingredient moiety becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. If the approved generic drug is both bioequivalent and pharmaceutically equivalent to the listed drug, the agency may assign a code to the product in an FDA publication that will represent a determination by the agency that the product is therapeutically equivalent to the listed drug. This designation will be considered by third parties in determining whether the generic drug will be utilized as an alternative to the listed drug.

Other Government Regulations

In addition to laws and regulations enforced by the FDA, we are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state or local laws and regulations, as our research and development involves the controlled use of hazardous materials, chemicals, viruses and various radioactive compounds.

Market Exclusivity

The commercial success of a product, once it is approved for sale, will primarily depend on a company's ability to create and sustain market share and exclusivity. Market exclusivity can be created and maintained by a number of methods, including, but not limited to: patents, trade secrets, know-how, trademarks, branding and a variety of market exclusivity provisions. The primary marketing exclusivity provision in the anti-cancer field is in the Orphan Drug Act.

Orphan Drug Designation

The United States, EU, Japan and Australia all have an enacted an "orphan drug" or rare disease program for drugs intended to treat a "rare disease or condition," which is generally a disease or condition that affects fewer than 200,000 persons (United States standard). Orphan drug designation must be requested before submitting for approval. After the granting of a orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has orphan drug designation subsequently receives marketing approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, which means the regulatory authority may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years in the United States, ten years in Europe and Japan and four years in Australia.

Orathecin has received orphan drug designation from the FDA and the European Agency for the Evaluation of Medical Products (the European Union equivalent of the FDA) for treatment of patients with refractory pancreatic cancer. Dacogen also received orphan drug designation from the FDA and European Agency for the Evaluation of Medical Products for MDS and sickle cell anemia.

Patents and Proprietary Technology

Patents are very important to us in establishing proprietary rights to the products we develop or license. The patent positions of pharmaceutical and biotechnology companies, including the Company, can be uncertain and involve complex legal, scientific, and factual questions. See *"Risk Factors—Our ability to protect our intellectual property rights will be critically important to the success of our business, and we may not be able to protect these rights in the United States or abroad."*

We actively pursue a policy of seeking patent protection when applicable for our proprietary products and technologies, whether they are developed in-house or acquired from third parties. We attempt to protect our intellectual property position by filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. To date, we have acquired licenses to or assignments of over 40 United States patents covering various aspects of our proprietary drugs and technologies, including 34 patents for various aspects of Orathecin and related products, five patents under our Nipent product portfolio, although none covers the use of Nipent for the treatment of hairy cell leukemia, five patents for our paclitaxel related products, one patent for Dacogen used in combination with an anti-neoplastic agent for the treatment of cancer, and two patents for our Surface Safe products. These issued United States patents will begin to expire in October 2012. We have been granted patents and have received patent licenses relating to our proprietary formulation technology, non-oncology and Partaject technologies, among which at least five patents are issued or licensed to us. In addition, we are prosecuting a number of patent applications for drug candidates that we are not actively developing at this time.

There can be no assurance that the patents granted or licensed to us will afford adequate legal protection against competitors or provide significant proprietary protection or competitive advantage. The patents granted or licensed to us could be held invalid or unenforceable by a court, or infringed or

circumvented by others. In addition, third parties could also obtain patents that we would need to license or circumvent. Competitors or potential competitors may have filed patent applications or received patents, and may obtain additional patents and proprietary rights relating to proteins, small molecules, compounds, or processes that are competitive with those of the Company.

In general, we obtain licenses from various parties that we deem to be necessary or desirable for the development, manufacture, use, or sale of our products or product candidates. Some of our proprietary products are dependent upon compliance with numerous licenses and agreements. These licenses and agreements may require us to make royalty and other payments, to reasonably exploit the underlying technology of applicable patents, and to comply with regulatory filings. If we fail to comply with these and other terms in these licenses and agreements, we could lose the underlying rights to one or more of these potential products, which would adversely affect our product development and harm our business.

We also have patents or licenses to patents issued outside of the United States, including Europe, Australia, Japan, Canada, Mexico and New Zealand. In addition, we have patent applications pending in these regions and countries as well as in China, Hungary and Israel. Limitations on patent protection in these countries, and the differences in what constitutes patentable subject matter in these countries outside the United States, may limit the protection we have on patents issued or licensed to us outside of the United States. In addition, laws of foreign countries may not protect our intellectual property to the same extent as would laws in the United States. To minimize our costs and expenses and to maintain effective protection, we focus our patent and licensing activities within the EU, Canada and Japan. In determining whether or not to seek a patent or to license any patent in a certain foreign country, we weigh the relevant costs and benefits, and consider, among other things, the market potential and profitability, the scope of patent protection afforded by the law of the jurisdiction and its enforceability, and the nature of terms with any potential licensees. Failure to obtain adequate patent protection for our proprietary drugs and technology would impair our ability to be commercially competitive in these markets.

Trade Secrets and Trademarks

We also rely on trade secret protection for certain proprietary technology. To protect our trade secrets, we pursue a policy of having our employees and consultants execute proprietary information agreements upon commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the relationship is confidential except in specified circumstances.

Registrations and applications for registration of our trademarks and service marks are pending as follows:

- Nipent (registered in the United States and Canada; application pending in Mexico);
- Orathecin (applications pending in the United States, Canada and Europe);
- Dacogen (application pending in the United States);
- Mitozytrex (FDA approved mark for anti-cancer compound; applications pending in the United States, Canada and in Europe);
- Partaject (applications pending in the United States, Canada and Europe);
- Surface Safe (mark for towelettes with antibiotic and antiviral properties; and registered in the US; application pending in Canada).

In addition, our "green bubbles" logo is registered in the United States, and our company name, SuperGen, is registered in the United States for use in pharmaceutical sales, and is the subject of

pending applications for those goods in Europe, as well as for manufacturing services in the United States.

Competition

The pharmaceutical industry in general and oncology sector in particular is highly competitive and subject to significant and rapid technological change. There are many companies, both public and private, including well-known pharmaceutical companies that are engaged in the development and sale of pharmaceutical products for some of the applications that we are pursuing. Our competitors and probable competitors include Aventis, Berlex Laboratories, Bristol-Myers Squibb Company, Eli Lilly & Co., Glaxo Smithkline, Novartis, Pfizer, Pharmion Corp., and others.

Many of our competitors and research institutions are addressing the same diseases and disease indications and working on products to treat such diseases as we are, and have substantially greater financial, research and development, manufacturing and marketing experience and resources than we do and represent substantial long-term competition for us. Some of our competitors have received regulatory approval of or are developing or testing product candidates that compete directly with our product candidates. For example, while we received orphan drug status for Orathecin and there is currently no competitor in the oral delivery market for the treatment of pancreatic cancer, there are approved drugs for the treatment of pancreatic cancer, including gemcitabine by Eli Lilly. In addition, Berlex Laboratories' fludarabine competes with Nipent in the leukemia market and Dacogen faces potential competition from Pharmion's azacitidine, if approved by the FDA.

In addition, many of these competitors, either alone or together with their customers, have significantly greater experience than we do in developing products, undertaking pre-clinical testing and clinical trials, obtaining FDA and other regulatory approvals, and manufacturing and marketing products. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or commercializing products before we do. If we commence commercial product sales of our product candidates, we will be competing against companies with greater marketing and manufacturing capabilities, areas in which we have limited or no experience. See "*Risk Factors—If we fail to compete effectively against other pharmaceutical companies, our business will suffer.*"

Factors affecting competition in the pharmaceutical industry vary depending on the extent to which the competitor is able to achieve a competitive advantage based on proprietary technology. If we are able to establish and maintain a significant proprietary position with respect to our proprietary products, competition will likely depend primarily on the effectiveness of the product and the number, gravity and severity of its unwanted side effects as compared to alternative products.

Extensive research and development efforts and rapid technological progress characterize the industry in which we compete. Although we believe that our proprietary position may give us a competitive advantage with respect to our key oncology drug candidates, we expect competition over development of new products to continue. Discoveries by others may render our current and potential products noncompetitive. Our competitive position also depends on our ability to attract and retain qualified scientific and other personnel, develop effective proprietary products, implement development and marketing plans, obtain patent protection and secure adequate capital resources.

Employees

As of December 31, 2003, we had 116 full-time employees. We use consultants and temporary employees to complement our staffing. Our employees are not subject to any collective bargaining agreements, and we consider our relations with employees to be good.

Geographic Area Financial Information

We operate in one business segment—human therapeutics. In 2003, 2002 and 2001, 97 percent of our sales were made in the United States and 3 percent in the EU.

Available Information

We are subject to the information requirements of the Securities Exchange Act of 1934, or the Exchange Act. Therefore, we file periodic reports, proxy statements, and other information with the Securities and Exchange Commission, or SEC. Such reports, proxy statements, and other information may be obtained by visiting the Public Reference Room of the SEC at 450 Fifth Street, NW, Washington, DC 20549 or by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains a website (*www.sec.gov*) that contains reports, proxy and information statements, and other information regarding issuers that file electronically.

Financial and other information about us is available on our website at www.supergen.com. We make available on our website, free of charge, copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the SEC. Information on our website does not constitute a part of this annual report on Form 10-K.

ITEM 2. PROPERTIES.

Our principal administrative facility is currently located in leased general office space, containing approximately 50,000 square feet, in Dublin, California, under a lease that expires in November 2010. Our laboratory operations are located in a 10,000 square foot industrial building that we own in Pleasanton, California. We also possess a five year lease to a 20,000 square foot office/warehouse space, adjacent to our laboratory facility, that is currently being subleased. We believe the above properties are suitable for our operations in the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS.

On April 14, 2003, John R. Blum filed a class action complaint entitled *John R. Blum v. SuperGen, Inc., et al.,* No. C 03-1576 in the U.S. District Court for the Northern District of California, against us and our former president and chief executive officer alleging violations of the Exchange Act and seeking unspecified damages. Subsequently, six similar actions were filed in the same court. Each of the complaints purported to be a class action lawsuit brought on behalf of persons who purchased or otherwise acquired our common stock during the period of April 18, 2000 through March 13, 2003, inclusive (except that one complaint specified the period as between April 18, 2000 through March 14, 2003). The complaints alleged that during such period, we issued materially false and misleading statements and failed to disclose certain key information regarding Mitozytrex. The complaints did not specify the amount of damages sought. In July 2003, each of the plaintiffs elected to voluntarily dismiss their respective complaints without prejudice. Each of the dismissals has been approved and entered by the court. We have not made any monetary payments and have no obligation to make any monetary payments whatsoever or any other obligations to any of the plaintiffs or their counsel in connection with the dismissals.

We are not currently subject to any pending material legal proceedings.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

A Special Meeting of Stockholders was held on December 18, 2003. The results of the voting are as follows:

Proposal 1: Proposal to approve the issuance of common stock at the company's election in connection with the payment of principal and interest amounts due under the company's senior convertible notes:

Votes For:	12,445,432
Votes Against:	4,585,201
Votes Abstaining:	1,299,491

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

Market for Common Stock

Our common stock trades on the Nasdaq National Market under the symbol "SUPG." The following table sets forth the high and low sales information for our common stock for each quarterly period in the two most recent fiscal years as reported on the Nasdaq National Market:

	High	Low
2003		
Quarter ended March 31, 2003	$ 4.05	$2.10
Quarter ended June 30, 2003	7.24	2.77
Quarter ended September 30, 2003	8.65	4.11
Quarter ended December 31, 2003	11.40	7.44
2002		
Quarter ended March 31, 2002	$14.52	$4.15
Quarter ended June 30, 2002	7.87	4.05
Quarter ended September 30, 2002	7.10	1.68
Quarter ended December 31, 2002	4.77	1.40

Equity Compensation Plan Information

The following table provides certain information with respect to all of our equity compensation plans in effect as of the end of December 31, 2003:

Plan Category	(A) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants, and Rights(1)	(B) Weighted-average Exercise Price of Outstanding Options, Warrants, and Rights	(C) Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column A)(2)
Equity compensation plans approved by security holders	5,326,349	$9.34	2,733,903
Equity compensation plans not approved by security holders	—	—	—
Total	5,236,349	$9.34	2,733,903

(1) Consists of securities issuable under the 2003 Stock Plan, the 1993 Stock Option Plan and the 1996 Directors' Option Plan.

(2) Includes 2,474,033 shares issuable under the 2003 Stock Option Plan, 220,000 shares issuable under the 1996 Directors' Option Plan, and 39,870 shares issuable under the 1998 Employee Stock Purchase Plan.

Holders of Record

As of February 27, 2004, there were 602 holders of record of the common stock and approximately 22,900 beneficial stockholders.

Dividends

We have never paid cash dividends on our capital stock and do not expect to pay any dividends in the foreseeable future. We intend to retain future earnings, if any, for use in our business.

Recent Sales of Unregistered Securities

None

ITEM 6. SELECTED FINANCIAL DATA.

The information set forth below is not necessarily indicative of results of future operations and should be read in conjunction with the financial statements and notes thereto appearing in Item 15 of Part IV of this report.

	Year ended December 31,				
	2003	2002	2001	2000	1999
	(Amounts in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Total revenue	$ 11,494	$ 15,269	$ 11,451	$ 7,089	$ 4,744
Cost of sales	3,865	4,491	2,727	1,641	2,032
Research and development	26,312	29,895	47,833	31,387	17,346
Selling, general and administrative	24,436	23,525	22,079	15,964	10,517
Acquisition of in-process research and development	—	—	—	1,585	10,850
Loss from operations	(43,119)	(42,642)	(61,188)	(43,488)	(36,001)
Other income (expense)	(10,351)	(6,829)	5,622	8,205	(984)
Net loss	$(53,470)	$(49,471)	$(55,566)	$(35,283)	$(36,985)
Basic and diluted net loss per common share	$ (1.56)	$ (1.52)	$ (1.69)	$ (1.04)	$ (1.58)
Shares used to compute basic and diluted net loss per common share	34,276	32,542	32,925	33,822	23,352

	As of December 31,				
	2003	2002	2001	2000	1999
Balance Sheet Data:					
Cash, cash equivalents, marketable securities, investments, and restricted cash and investments	$ 40,067	$ 39,982	$ 77,359	$133,815	$ 29,366
Other current assets	8,894	9,744	5,807	7,541	11,001
Property, plant and equipment, net	4,420	5,443	6,345	5,438	2,923
Other assets	1,355	2,164	33,206	16,539	10,188
Total assets	$ 54,736	$ 57,333	$122,717	$163,333	$ 53,478
Convertible debt, net of discounts	$ 13,593	$ —	$ —	$ —	$ —
Other current liabilities	11,821	7,548	12,752	10,221	4,543
Non-current liabilities	2,475	1,783	2,167	3,167	4,167
Stockholders' equity	26,847	48,002	107,798	149,945	44,768
Total liabilities and stockholders' equity	$ 54,736	$ 57,333	$122,717	$163,333	$ 53,478
Cash dividends per share	—	—	—	—	—

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Our disclosure and analysis in this section of the report also contain forward-looking statements. When we use the words "anticipate," "estimate," "project," "intend," "expect," "plan," "believe," "should," "likely" and similar expressions, we are making forward-looking statements. Forward-looking statements provide our current expectations or forecasts of future events. In particular, these statements include statements such as: the timing of receiving FDA acceptance with respect to our submission of an NDA for Orathecin; the timing of our filing of an NDA for Dacogen; our estimates about becoming profitable; our forecasts regarding our research and development expenses; the impact of our outstanding indebtedness; and our statements regarding the sufficiency of our cash to meet our operating needs. Our actual results could differ materially from those predicted in the forward-looking statements as a result of risks and uncertainties including, but not limited to, delays and risks associated with conducting and managing our clinical trials, developing products and obtaining regulatory approval; ability to establish and maintain collaboration relationships; competition; ability to obtain funding; ability to protect our intellectual property; our dependence on third party suppliers; risks associated with the hiring and loss of key personnel; adverse changes in the specific markets for our products; ability to launch and commercialize our products. Certain unknown or immaterial risks and uncertainties can also affect our forward-looking statements. Consequently, no forward-looking statement can be guaranteed and you should not rely on these forward-looking statements. For a discussion of the known and material risks that could act our actual results, please see "Factors Affecting Future Operating Results" in this section of the report. We undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

We are a pharmaceutical company dedicated to the development and commercialization of therapies for solid tumors, hematological malignancies, and blood disorders. Our strategy is to commercialize products by minimizing the time, expense and technical risk associated with drug research through identifying and acquiring pharmaceutical compounds in the later stages of development. Our primary objective is to become a leading supplier of therapies for solid tumors, hematological malignancies, and blood disorders.

Since our incorporation in 1991 we have devoted substantially all of our resources to our product development efforts. Currently we have three key compounds, Orathecin, Dacogen and Nipent, that are the focus of our efforts.

Orathecin. We recently completed three randomized Phase III studies for Orathecin and submitted our NDA for filing with the FDA on January 26, 2004. The submission of this NDA represents a significant milestone in our history and is the culmination of years of research and development. Because we submitted our NDA under accelerated approval procedures, if it is accepted for filing by the FDA, our NDA will receive expedited substantive review within six months, however, the FDA may not accept our submission for filing, and even if it does so, there can be no guarantee that the FDA will approve Orathecin.

Dacogen. We are compiling and validating the results from our Phase III clinical studies of Dacogen in the treatment of MDS. In May 2003, we were granted "fast track" designation for Dacogen in the treatment of MDS. If the Phase III final results are positive, we anticipate submitting the initial modules of à "rolling" NDA for Dacogen in the treatment of MDS to the FDA in 2004.

Nipent. Nipent is approved by the FDA and marketed by us for the treatment of hairy cell leukemia. Nipent has also shown promise in other diseases and we are conducting a series of

post-marketing Phase IV clinical trials for CLL, NHL, cutaneous and peripheral T-cell lymphomas and GvHD.

Other Products. Our portfolio of other products includes Partaject-delivered busulfan, and inhaled versions of Orathecin and paclitaxel. We also market Surface Safe. We have also received regulatory approval to market our generic daunorubicin for a variety of acute leukemias and Mitozytrex (mitomycin for injection), for use in the therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed. Moreover, we hold United States sales and marketing rights to the cancer vaccine Avicine. We are continually evaluating our product portfolio to determine whether it is appropriate for us to dedicate the resources needed to commercialize these products ourselves or whether we would be better served selling or licensing the rights to develop these products to third parties.

To date, our product revenues have been limited and are derived primarily from sales of Nipent, which we are marketing in the United States for the treatment of hairy cell leukemia. Most of our products are still in the development stage, and we will require substantial additional investments in research and development, clinical trials, and in regulatory and sales and marketing activities to commercialize current and future product candidates. Conducting clinical trials is a lengthy, time-consuming, and expensive process involving inherent uncertainties and risks, and our studies may be insufficient to demonstrate safety and efficacy to support FDA approval of any of our product candidates.

As a result of our substantial research and development expenditures and minimal product revenues, we have incurred cumulative losses of $286.7 million through December 31, 2003, and have never generated enough funds through our operations to support our business. We expect to continue to incur operating losses at least through 2005. This is due primarily to marketing launch expenditures for Orathecin and Dacogen, if approved, as well as projected spending for the ongoing clinical trials and related development of our product candidates.

Ultimately, our ability to become profitable will depend upon a variety of factors, including regulatory approvals of our products, the timing of the introduction and market acceptance of our products and competing products, increases in sales and marketing expenses related to the launch of Orathecin and Dacogen, if approved, and our ability to control our costs. If the results from our clinical trials, especially in the case of Dacogen, are not positive, we may not be able to get sufficient funding to continue our trials or conduct new trials, and we would be forced to scale down or cease our business operations. Moreover, if Orathecin or Dacogen are not approved or commercially accepted we will remain unprofitable for longer than we currently anticipate. Additionally, we might be forced to substantially scale down our operations or sell certain of our assets, and it is likely the price of our stock would decline precipitously.

Critical Accounting Policies

Our management discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and reported disclosures. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, intangible assets, valuation of investments and derivative instruments. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent

from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully disclosed in Note 1 to our consolidated financial statements. However, some of our accounting policies are particularly important to the portrayal of our financial position and results of operations and require the application of significant judgment by our management. We believe the following critical accounting policies, among others, affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

Our net sales relate principally to Nipent and, to a lesser extent, mitomycin. We recognize sales revenue upon shipment and related transfer of title to customers, and collectibility is reasonably assured. Allowances are established for estimated product returns and exchanges. Cash advance payments received in connection with distribution agreements or research grants are deferred and recognized ratably over the period of the respective agreements or until services are performed.

Allowances for product returns and exchanges are based on historical information and known trends from external sources. The costs of product exchanges, which include actual product costs and related shipping charges, are included in cost of sales. In estimating returns, we analyze historical returns and sales patterns, the remaining shelf life of inventory, and changes in demand. We continually assess our historical experience and adjust our allowances as appropriate. If actual product returns and exchanges are greater than our estimates, additional allowances may be required.

Intangible Assets

We have intangible assets related to goodwill and other acquired intangibles such as trademarks, covenants not to compete, and customer lists. The determination of related estimated useful lives and whether or not these assets are impaired involves significant judgment. Changes in strategy and/or market conditions could significantly impact these judgments and require adjustments to recorded asset balances. We review intangible assets, as well as other long-lived assets, for impairment whenever events or circumstances indicate that the carrying amount may not be fully recoverable.

Valuation of Investments in Financial Instruments

Investments in financial instruments are carried at fair value with unrealized gains and losses included in accumulated other comprehensive income or loss in stockholders' equity. Our investment portfolio includes equity securities that could subject us to material market risk and corporate obligations that subject us to varying levels of credit risk. If the fair value of a financial instrument has declined below its carrying value for a period in excess of six consecutive months or if the decline is due to a significant adverse event, such that the carrying amount of these investments may not be fully recoverable, the impairment is considered to be other than temporary. An other than temporary decline in fair value of a financial instrument would be subject to a write-down resulting in a charge against earnings. The determination of whether a decline in fair value is other than temporary requires significant judgment, and could have a material impact on our balance sheet and results of operations. Our management reviews the securities within our portfolio for other than temporary declines in value on a regular basis. The prices of some of our marketable securities, in particular AVI, are subject to considerable volatility. Decreases in the fair value of these securities may significantly impact our results of operations.

Investments in equity securities without readily determinable fair value are carried at cost. We periodically review those carried costs and evaluate whether an impairment has occurred. The determination of whether an impairment has occurred requires significant judgment, as each investment may have unique market or development opportunities.

Derivative Instruments

In connection with the June 2003 convertible debt transaction, we issued to the note holders warrants to purchase 2,634,211 shares of common stock of AVI at $5.00 per share. As of December 31, 2003, we owned sufficient shares of AVI to cover the potential obligation. These warrants are considered to be a derivative and have been recorded on the balance sheet at fair value. The accounting for derivatives is complex, and requires significant judgments and estimates involved in determining the fair value in the absence of quoted market values. These estimates are based on valuation methodologies and assumptions deemed appropriate in the circumstances. The fair value of the warrants is based on various assumptions input into the Black-Scholes pricing model. Such assumptions include the estimated market volatility and interest rates used in the determination of fair value. The use of different assumptions may have a material effect on the estimated fair value amount and the results of operations.

Results of Operations

Year ended December 31, 2003 compared with year ended December 31, 2002:

Revenues

	2003	2002	Change Dollar	Change Percent
		(in thousands)		
Revenues	$11,494	$15,269	$(3,775)	(24.7)%

The decrease in revenues in 2003 was due primarily to lower sales of Nipent, our drug currently approved for the treatment of hairy cell leukemia. Nipent sales were $10.1 million in 2003 compared to $12.6 million in 2002. The decline in Nipent sales was due to an increase in wholesaler purchases prior to a price increase that went into effect at the beginning of the fourth quarter 2003, which resulted in a significant decline in sales in the fourth quarter, which traditionally had been a high-volume quarter. In addition, the price increase had an impact on the average wholesale price, a key determining factor in Medicare reimbursement, and resulted in lower than expected demand for Nipent as the reimbursement for Nipent was impacted. Sales in 2003 included approximately $315,000 in sales to Europe, compared to $400,000 in 2002. Unlike our Nipent sales efforts in the U.S. market where we call on clinicians directly, our role in Europe is currently limited to that of a supplier. As such, we have not had a direct influence on Nipent sales at the clinical level, making their timing and magnitude difficult to predict and dependent on the efforts of our European distributor. In early 2004, we acquired marketing rights to Nipent in Europe, which may help improve sales and gross margins of Nipent.

Cost of sales

	2003	2002	Change Dollar	Change Percent
		(in thousands)		
Cost of sales	$3,865	$4,491	$(626)	(13.9)%

Cost of sales as a percentage of net sales revenue was 34 percent in 2003 compared to 32 percent in 2002. The increase in cost of sales percentage in 2003 is due to a larger portion of our sales being related to generic mitomycin, which is sold at lower margins than Nipent. In addition, raw material costs for mitomycin increased in 2003. Current margins may not be indicative of future margins due to possible variations in product mix, average selling prices, and manufacturing costs.

Research and development expenses

	2003	2002	Change Dollar	Change Percent
		(in thousands)		
Research and development	$26,312	$29,895	$(3,583)	(12.0)%

The decrease in research and development expenses was due primarily to lower expenditures relating to our Phase I/II and Phase III clinical trials of Orathecin, which declined by $3.6 million in 2003 over 2002. Most of our Phase I/II studies of Orathecin in various indications were completed in late 2002. In addition, we completed enrollment of over 1,800 patients into the three Phase III Orathecin trials for pancreatic cancer in 2001, and the expenditures for these trials continue to decline as patients complete the studies. Although the Phase III clinical trials for Dacogen increased by $660,000 from 2002 to 2003, the Phase III trials conducted for Dacogen have not been as costly as the Orathecin trials.

We conduct research internally and also through collaborations with third parties, and we intend to maintain our strong commitment to our research and development efforts in the future. Our research and development activities consist primarily of clinical development and the related advancement of our existing product candidates through clinical trials. Our major research and development projects include Orathecin, Dacogen, and studies of other indications of Nipent. We have focused much of our attention and resources on developing Orathecin, and from 1998 through 2003, we have spent approximately $65 million on the Orathecin program. From 2000 through 2003, we have spent approximately $7.9 million on the development of and clinical studies related to Dacogen, and from 1998 through 2003, we have spent approximately $12.5 million on Phase I, II/III, and Phase IV programs related to different indications of Nipent. Conducting clinical trials is a lengthy, expensive and uncertain process. Completion of clinical trials may take several years or more. The length of time generally varies substantially according to the type, complexity, novelty and intended use of the product candidate. Our clinical trials may be suspended at any time if we or the FDA believe the patients participating in our studies are exposed to unacceptable health risks. We may encounter problems in our studies which will cause us or the FDA to delay or suspend the studies. Because of these uncertainties, we cannot predict when or whether we will successfully complete the development of our product candidates or the ultimate product development cost.

Selling, general and administrative expenses

	2003	2002	Change Dollar	Change Percent
		(in thousands)		
Selling, general and administrative	$24,436	$23,525	$911	3.9%

The increase in Selling, general and administrative expenses consists of an increase in general and administrative expenses of $1.6 million, offset by decreases in sales and marketing expenses of approximately $675,000. The declines in sales and marketing expenses were attributed to lower salaries and bonuses, due to staff attrition that has not yet been replaced, as well as reduced spending on trade shows and conferences. The increase in general and administrative expenses was due to higher administrative salaries and bonuses, which included non-cash charges for stock compensation related to the modification of and acceleration of stock options associated with the change in status or departure of certain Company management, higher costs for investor relations and business development activities, and $625,000 relating to the write off of one of our equity investments.

Other income (expense)

	2003	2002	Change Dollar	Change Percent
		(in thousands)		
Interest income	$ 474	$ 1,662	$(1,188)	(71.4)%
Interest expense	(3,981)	—	3,981	—
Amortization of deemed discount on convertible debt	(13,738)	—	13,738	—
Change in valuation of derivative	6,894	—	6,894	—
Other than temporary decline in investments	—	(8,491)	(8,491)	—

The decrease in interest income was due to lower available cash and marketable securities balances and a decline in interest rates in 2003.

Interest expense in 2003 included $3.1 million of amortization of prepaid financing costs, and $900,000 in interest incurred on the 4% interest bearing convertible debt issued in February and June 2003. Non-cash amortization of deemed discount on the convertible debt was $13.7 million. No such amounts were recorded in 2002 as there was no debt issued in 2002.

Income related to the change in derivative valuation represents the change in the valuation of two separate derivatives. In our February 2003 exchangeable convertible debt transaction, the February Notes contained a feature that allowed holders of the notes to receive a portion of the principal and interest in 2,634,211 shares of AVI at $5.00 per share. The initial value ascribed to this derivative was $2.3 million. The ability of the note holders to exchange the notes into shares of AVI was eliminated in our June 2003 convertible debt transaction, so the entire derivative value at that time of $2.5 million was taken to other income. As part of the June 2003 convertible debt transaction and the February Notes restructuring, we issued to the note holders warrants to purchase 2,634,211 shares of AVI at $5.00 per share. These warrants represent a derivative instrument and were valued at $10.1 million using the Black-Scholes pricing model on June 24, 2003. Through December 31, 2003, the value of this derivative had decreased by $4.6 million. This change in value has been recorded as other income in 2003. As the fair value of the common stock of AVI has fluctuated significantly in the past two years and is expected to do so in the future given the volatility of the AVI stock, the valuation of the derivative in future periods may have a significant impact on our results of operations.

During 2002, we recorded an other than temporary decline in the value of our investments in the stocks of AVI, Peregrine Pharmaceuticals, Inc., and Inflazyme, Inc. We did not incur any similar other than temporary decline in the value of our investments in 2003.

Year ended December 31, 2002 compared with year ended December 31, 2001:

Revenues

	2002	2001	Change Dollar	Change Percent
		(in thousands)		
Revenues	$15,269	$11,451	$3,818	33.3%

Our revenues consist primarily of sales of Nipent, currently approved for the treatment of hairy cell leukemia. Our 2002 revenues included $12.1 million in Nipent sales in the United States and $800,000 in sales to the European distributor for Nipent. Revenues in 2001 included $9.7 million in U.S. Nipent sales and $338,000 in European sales.

Cost of sales

	2002	2001	Change Dollar	Change Percent
		(in thousands)		
Cost of sales	$4,491	$2,727	$1,764	64.7%

Cost of sales as a percentage of net sales revenues was 32 percent in 2002 compared to 26 percent in 2001. The increased cost of sale percentage in 2002 was primarily due to higher start-up and manufacturing costs and lower yield for Nipent as we qualified a new vendor to manufacture the drug in early 2002. To a lesser extent, the increase was due to higher sales of Nipent in Europe, which were made at a lower unit selling price under a supply agreement for sale outside North America.

Research and development expenses

	2002	2001	Change Dollar	Change Percent
		(in thousands)		
Research and development	$29,895	$47,833	$(17,938)	(37.5)%

The decline in research and development expenses was due primarily to the completion of enrollment in 2001 of over 1,800 patients into our Phase III clinical trials of Orathecin for pancreatic cancer. Although many of these patients remained on study into 2002, most of the clinical trial expenditures for these patients were incurred in 2001. In 2002 we began enrollment of patients into our Phase III trials for Dacogen, but these trials involved fewer patients and the clinical trial costs for this drug were lower than those for Orathecin.

Selling, general and administrative expenses

	2002	2001	Change Dollar	Change Percent
		(in thousands)		
Selling, general and administrative	$23,525	$22,079	$1,446	6.6%

The increase in Selling, general and administrative expenses was due primarily to higher expenditures for patent and copyright legal expenses, liability and life insurance, business development expenses of $906,000 relating to our European start-up operations, and administrative salaries and bonuses.

Other income (expense)

	2002	2001	Change Dollar	Change Percent
		(in thousands)		
Interest income	$ 1,662	$5,622	$(3,960)	(70.4)%
Other than temporary decline in value of investments	(8,491)	—	8,491	—

The decrease in interest income was due to lower available cash and investment balances and a decline in interest rates in 2002.

The $8.5 million represented an other than temporary decline in the value of our investments in AVI, Inflazyme, Inc., and Peregrine Pharmaceuticals, Inc. We had no such charges in 2001.

Liquidity and Capital Resources

Our cash, cash equivalents, and both short and long-term marketable securities totaled $14.6 million at December 31, 2003, compared to $22.4 million at December 31, 2002. In addition, at December 31, 2003 we held an additional $10.7 million in an interest bearing collateral account securing a portion of our convertible debt which is classified in current assets as "Restricted cash and investments". In addition, we held 2,684,211 shares of registered stock of AVI, most of which are held as security for the warrants we issued to convertible debt holders to purchase the 2,634,211 AVI shares at $5.00 per share. The AVI shares had a market value of $10.7 million at December 31, 2003, and are classified on the balance sheet under non-current "Restricted cash and investments."

The net cash used in operating activities in 2003 was $36.8 million, which consisted primarily of the net loss of $53.5 million, less $13.7 million non-cash amortization of deemed discount on our convertible debt, $3.1 million amortization of prepaid financing costs, $1.2 million in depreciation expense, and $4.9 million decline in accounts receivable, offset by $6.9 million non-cash change in the valuation of derivatives. The net cash used in operating activities in 2002 was $47.7 million, which consisted primarily of the net loss of $49.5 million, an increase in accounts receivable of $2.9 million and the reduction of accounts payable and other liabilities totaling $4.6 million, offset by the other than temporary decline in value of investments of $8.5 million. The net cash used in operating activities in 2001 was $49.8 million, which consisted primarily of the net loss of $55.6 million, offset by the increase in accounts payable and other liabilities of $2.5 million and the increase in other receivables of $1.3 million.

Net cash used in investing activities in 2003 was $5.0 million, which consisted primarily of $10.6 million raised in our June convertible debt transaction that was transferred to a cash collateral

account, and purchases of marketable securities of $8.1 million, offset by sales and maturities of marketable securities of $13.9 million. Net cash provided by investing activities in 2002 was $39.8 million, and primarily related to the sales and maturities of marketable securities of $72.7 million, net of purchases of $32.5 million. Net cash provided by investing activities in 2001 was $1.6 million, which consisted primarily of $3.8 million in sales and maturities of investments, net of purchases, offset by $2.2 million in purchased of property and equipment.

Net cash provided by financing activities was $39.6 million in 2003, due primarily to the issuance of a total of $42.5 million in convertible notes in separate transactions in February and June 2003, offset by the payment of $3.4 million in prepaid financing costs. Net cash used in financing activities was $2.6 million in 2002, and related primarily to issuances and repurchases of our common stock. Net cash used in financing activities in 2001 was $4.8 million, and related primarily to repurchases, net of issuances, of our common stock.

February Notes Financing. On February 26, 2003 we entered into a Securities Purchase Agreement with a number of purchasers for the private placement of senior exchangeable convertible notes, or the February Notes, in the principal amount of $21.25 million and related warrants. The February Notes accrue interest at a rate of four percent per year, and were, at the option of the investors, in whole or in part, (a) convertible into shares of our common stock at a fixed conversion price of $4.25 per share, or (b) exchangeable for up to 2,634,211 of our AVI shares at a fixed exchange price of $5.00 per share. We may pay interest due under the February Notes in shares of our common stock at a price tied to the then market price, and subject to certain conditions, we could have also elected to pay principal due under the February Notes in shares of our common stock and our AVI shares at prices tied to the then market price of our common stock and AVI common stock, respectively. Subject to certain conditions, at any time after the first anniversary of the effectiveness of a registration statement we filed to cover the resale of the securities, all of the outstanding February Notes would have been redeemable by us for a cash redemption price at 120 percent of par plus accrued and unpaid interest. Upon a change of control, the holders will have certain redemption rights, and we could have also redeemed the February Notes, in each case subject to certain conditions and provided that, in the event of our redemption, we would have issued to the holders of the February Notes certain warrants exercisable for the securities of the acquiring entity and the AVI shares. Our exchange obligations under the February Notes were secured by a pledge of the AVI shares. In connection with the issuance of the February Notes, we also issued warrants to the note holders for the purchase of an aggregate of 1,997,500 shares of our common stock. These warrants will be exercisable for a term of five years at an exercise price of $5.00 per share.

June Notes Financing and February Notes Restructuring. On June 24, 2003, we closed a private placement transaction in which we issued the June Notes, in the aggregate principal amount of $21.25 million, to the same holders of our outstanding February Notes. The June Notes are payable in four equal quarterly installments beginning March 31, 2004, and accrue interest at a rate of four percent per year. Pursuant to the terms of the June Notes, the note holders may elect to convert, at any time prior to maturity, their June Notes into shares of our common stock at a fixed price of $6.36. We may also elect to pay the principal and interest then due under the June Notes, subject to certain conditions, through the issuance of shares of our common stock at a conversion price equal to: (a) with respect to the interest payment, 95 percent of the arithmetic average of the weighted average price of our common stock on each of the five consecutive trading days immediately preceding payment and (b) with respect to the principal payment, as of any date of determination, 90 percent of the arithmetic average of the weighted average price of our common stock on any 15 trading days designated by the note holders during the 20 trading days immediately preceding such date. In addition, the note holders have a right of first refusal to purchase their pro rata portion of the greater of one-third of the securities offered by us for sale or $5.0 million worth of such offered securities.

Concurrent with the issuance of the June Notes, we restructured our outstanding February Notes. Pursuant to the restructuring, the holders of the February Notes converted half of the principal amount ($10,625,000) plus accrued and unpaid interest thereon into shares of our common stock at the fixed conversion price of $4.25, thereby causing the remaining $10,625,000 principal amount of the outstanding February Notes to have a final maturity date of February 26, 2004, which has been paid subsequent to December 31, 2003 with shares of our common stock. The remaining February Notes were amended to remove the feature permitting the holders to exchange such notes into the AVI shares at an exchange price of $5.00, and to remove our ability to use the AVI shares valued at market at the time of repayment to repay the outstanding principal amount.

In addition, in connection with the issuance of the June Notes and the restructuring of the February Notes, we issued to the note holders warrants to purchase the 2,634,211 AVI shares at an exercise price of $5.00 per share.

While the full amount of the $21,250,000 proceeds from the June Notes were transferred to us, $10,625,000 of such funds were placed into an interest bearing collateral account, and not available for our use until release. Absent certain defaults by us, $5,312,500 (one-half of the $10,625,000) will be available to us on March 24, 2004, and the remaining $5,312,500 will be available on June 24, 2004. We expect to be able to repay the June notes with shares of our common stock.

Our contractual obligations as of December 31, 2003 are as follows (in thousands):

	Payments Due by Period				
	Total	<1 year	1-3 years	4-5 years	After 5 years
Operating leases, net	$14,994	$ 2,017	$6,340	$4,471	$2,166
Convertible debt	26,250	26,250	—	—	—
Long term obligations—contractually obligated research funding	2,170	325	1,145	670	30
Total contractual cash obligations	$43,414	$28,592	$7,485	$5,141	$2,196

The operating lease obligations noted above are net of sublease income of $516,000. The contractually obligated research funding noted above consists primarily of required payments to Peregrine, RTP Pharma and The Clayton Foundation. We are also obligated to potentially expend up to a total of $88.0 million in milestone and development related payments to AVI and Peregrine for development of Avicine and VEGF technologies, respectively. We are unable to determine precisely when and if our payment obligations under our agreements with AVI and Peregrine will become due as these obligations are based on milestone events the achievement of which is subject to a significant number of risks and uncertainties. Because some of the milestone events are revenue-related and payment obligation would not be triggered absent our receipt of revenues from the relationship, we may be able to use funds generated from these relationships to make the milestone payments.

We have financed our operations primarily through the issuance of equity and debt securities and the receipt of milestone payments in connection with collaborative agreements. We believe that our current cash, cash equivalents, marketable securities and other investments will satisfy our cash requirements through at least December 31, 2004. However, it is our intention to pursue additional financing options, including the selling of additional shares of stock in a public or private offering and/or exploring marketing partnership opportunities for Orathecin, Dacogen and Nipent.

We believe that our need for additional funding will increase in the future, especially if we receive regulatory approval for Orathecin and Dacogen, and that our continued ability to raise funds from external sources will be critical to our success. We continue to actively consider future contractual arrangements that would require significant financial commitments. If we experience currently unanticipated cash requirements, we could require additional capital much sooner than presently

anticipated. We may raise money by the sale of our equity securities or debt, or the exercise of outstanding warrants and stock options by the holders of such warrants or options. However, given uncertain market conditions and the volatility of our stock price, we may not be able to sell our securities in public offerings or private placements at prices and on terms that are favorable to us, if at all. We may also choose to obtain funding through licensing and other contractual agreements. Such arrangements may require us to relinquish our rights to our technologies, products or marketing territories, or to grant licenses on terms that are not favorable to us. If we fail to obtain adequate funding in a timely manner, or at all, we will be forced to scale back our product development activities, or our operations in a manner that will ensure we can discharge our obligations as they come due in the ordinary course of business at least through December 31, 2004.

Related Party Transactions

EuroGen Pharmaceuticals Ltd.

In September 2001, we entered into a Supply and Distribution Agreement with EuroGen Pharmaceuticals Ltd., a company incorporated and registered in England and Wales. The agreement was based on arm's length negotiation between the parties. Under the agreement, we granted EuroGen the exclusive European and South African rights to promote and sell certain of our existing generic and other products or compounds. The agreement also establishes a process for granting EuroGen rights to sell additional products in Europe and South Africa, subject to our compliance with our other then existing licensing and distribution arrangements. After complying with these existing obligations, we will be required to offer EuroGen the option to obtain European and South African rights to our future products. EuroGen will seek and pay for all regulatory approvals and authorizations necessary for the commercial sale of the products in the territories where they market and sell the products. During 2001 we loaned EuroGen $260,000 under a line of credit arrangement designed to cover start-up expenses. During 2002, we advanced an additional $646,000 to EuroGen to fund its operations. In December 2002, all but one of the other investors in EuroGen withdrew their ownership interests in the entity, and we became 95 percent owners of EuroGen. Larry Johnson, the president and chief executive officer of EuroGen, owns the remaining five percent. The amounts advanced to EuroGen, including the amounts advanced in 2001, totaling $906,000 were charged to Selling, general, and administrative expense in 2002. In 2003 we have included the results of EuroGen in our consolidated operations as they are a subsidiary and accordingly, in 2003, $325,000 has been charged to Selling, general, and administrative expense.

KineMed, Inc.

In November 2001, we made an equity investment of $150,000 to acquire 100,000 shares of Series A Convertible Preferred stock of KineMed, Inc., a start-up biotech company, and in March 2003 we invested an additional $30,000 to acquire 15,000 shares. The president and chief executive officer of KineMed is one of our former directors. Our chief executive officer is a member of the board of directors of KineMed. We have accounted for this investment under the cost method as our ownership is less than 20 percent of KineMed's outstanding shares. This investment is included on the balance sheet in Investment in stock of related parties.

AVI BioPharma, Inc.

In December 1999, we entered into an agreement with AVI. At the time, the chief executive officer of AVI was a member of our board of directors. He later resigned from our board in May 2002. Our former president and chief executive officer is a member of the board of directors of AVI. The transaction was approved by members of our board of directors who had no interest in the transaction and evaluated the transaction with input from members of our financial and scientific staffs. We currently own 2,684,211 shares of AVI common stock.

Under the terms of the agreement, we acquired one million shares of AVI common stock, which amounted to approximately 7.5 percent of AVI's outstanding common stock, for $2.5 million cash and 100,000 shares of our common stock at $28.25 per share. We also acquired exclusive negotiating rights for the United States market for Avicine, AVI's proprietary cancer vaccine currently in late-stage clinical testing against a variety of solid tumors. Avicine is an immunotherapy that neutralizes the effect of a tumor-associated antigen on cancer cells, while stimulating the body's immune system to react against the foreign tumor.

In July 2000, we finalized an agreement with AVI to obtain the United States marketing rights for Avicine. We issued 347,826 shares of our common stock along with $5.0 million in cash to AVI as payment for our investment, in exchange for 1,684,211 shares of AVI common stock. As part of this agreement, we obtained the right of first discussion to all of AVI's oncology compounds and an option to acquire an additional ten percent of AVI's common stock for $35.625 per share. This option is exercisable for a three-year period commencing on the earlier of the date the FDA accepts for filing the NDA submitted for Avicine or the date on which the closing price of AVI's common stock exceeds the option exercise price. Our ownership is less than 20 percent of AVI's outstanding shares. The investment is classified as available-for-sale. No value has been ascribed to the option as neither of the measurements have been achieved as of December 31, 2003.

Avicine will require significant additional expenditures to complete the clinical development necessary to gain marketing approval from the FDA and equivalent foreign regulatory agencies. As part of this agreement, we are obligated to make additional payments to AVI based on successful achievement of developmental, regulatory approval, and commercialization milestones over the next several years that could total $80.0 million. In 2001, we recorded $1.2 million in research and development expenses relating to our share of the development costs for Avicine. At December 31, 2001, this amount had not been paid to AVI and was presented on the balance sheet as Payable to AVI BioPharma, Inc. This amount was paid in 2002. In 2002, we recorded $421,000 in research and development expenses for Avicine and in 2003 we recorded an additional $144,000 in research and development expenses. At December 31, 2003, the $565,000 total was still payable and is presented on the balance sheet as Payable to AVI BioPharma, Inc.

AMUR Pharmaceuticals, Inc.

Two of our current directors and two former directors were formerly directors of AMUR, a privately-held company conducting research and development work partially funded by us. The president of AMUR performed consulting services for us and was paid $15,000 in 2003, $180,000 in 2002, and $180,000 in 2001 for these consulting services.

In September 2000, we acquired all of the intellectual property of AMUR in exchange for 37,795 shares of our common stock and two-year warrants to purchase 200,000 shares of our common stock at $40.00 per share. During 2002, these warrants were extended for two additional years.

Quark Biotech, Inc.

Our current president and chief executive officer and our former president and chief executive officer who is currently one of our directors are each directors and stockholders of Quark Biotech, Inc., or QBI, a privately-held development stage biotechnology company. One of our former directors is currently the president and chief executive officer and a director of QBI and one of our former directors is also a director of QBI. In May 1997, we made an equity investment of $500,000 in QBI's preferred stock, which represents less than one percent of the company's outstanding shares as of December 31, 2003. Our investment in QBI is carried at cost and is included in Investment in stock of related parties. In November 1997, we leased approximately one-third of the laboratory square footage at the SuperGen Pharmaceutical Research Institute, or SPRI, to QBI for $3,000 per month for three

years, plus its pro-rata share of specified common expenses. We also completed certain building and laboratory improvements and purchased furniture on behalf of QBI for a total of approximately $750,000, of which $300,000 was reimbursed by QBI in 1997. In the first quarter of 2000, we terminated the lease with QBI and we took possession of the entire laboratory space and related property, plant, and equipment at SPRI.

In January 2002, we subleased a portion of our laboratory at SPRI to QBI. The initial term of the sublease expired on December 31, 2002, but we continued to sublease the space to QBI on a month-to-month basis through August 2003. We collected $123,000 in sublease income from QBI in 2002 and $56,000 in 2003.

The Kriegsman Group

In March 2001, we retained The Kriegsman Group to render advice and assistance with respect to financial public relations and promotions. In addition, in connection with such services, on March 22, 2001, we issued three warrants to The Kriegsman Group, two of which are still outstanding, and as amended in February 2003, the terms of the warrants are as follows: the "A" warrant for the purchase of 200,000 shares of common stock is exercisable at the exercise price of $10.47 and will expire in February 2006, and the "C" warrant for the purchase of 100,000 shares of common stock is exercisable at the exercise price of $10.47 and will expire in February 2007. On July 25, 2002, our former president and chief executive officer became a member of the board of directors of CytRx Corp. Steven Kriegsman, the president of The Kriegsman Group, is also a significant shareholder and president and chief executive officer of CytRx Corp. We paid The Kriegsman Group consulting fees of $220,000 in 2003, $240,000 in 2002, and $232,500 in 2001. In November 2003 we terminated all agreements with The Kriegsman Group.

Family Relationships

We employ a number of individuals who are immediate family members of Dr. Joseph Rubinfeld, our former president and chief executive officer and our current chief scientist and chairman emeritus. None of these family members are our officers or directors.

Recently Issued Accounting Standards

In January 2003, the Financial Accounting Standards Board, or FASB, issued FASB Interpretation No. 46, "Consolidation of Variable Interest Entities," or FIN 46. FIN 46 clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. In December 2003, the FASB issued a revision to FIN 46, or FIN 46R. FIN 46R provides a broad deferral of the latest date by which all public entities must apply FIN 46 to certain variable interest entities to the first reporting period ending after March 15, 2004. We do not expect the adoption of FIN 46 to have a material impact on our financial position, cash flows or results of operations.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity," which establishes standards for how an issuer of financial instruments classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or in some circumstances, as an asset) if, at inception, the monetary value of the obligation is based solely or predominantly on: (a) a fixed monetary amount known at inception, (b) variations in something other than the fair value of the issuer's equity shares or (c) variations inversely related to changes in the fair value of the issuer's equity shares. SFAS No. 150 is effective for financial

instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 did not have an impact on our financial statements.

Income Taxes

As of December 31, 2003, we have net operating loss carryforwards for federal income tax purposes of approximately $267.6 million which expire in the years 2005 through 2023, and federal research and development credit carryforwards of approximately $5.0 million, which expire in the years 2007 through 2023.

Factors Affecting Future Operating Results

Our business, future operating results and financial condition are dependent upon many factors that are subject to a number of risks and uncertainties. Below we summarize the material risks and uncertainties that are known to us and that may cause our future operating results to be different than our planned or projected results, and that may negatively affect our operating results and financial condition. However, the risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that are not presently known to us or that we currently believe are immaterial may also impair our business operations or financial condition.

Risks Related to Orathecin, Dacogen and Nipent

Our future success is highly dependent on regulatory approval and successful commercialization of Orathecin. If our submission for Orathecin does not support the acceptance for filing or approval of the NDA by the FDA for any reason, our business will be substantially harmed.

On January 26, 2004, we submitted an NDA to the FDA for approval of Orathecin for the treatment of patients with refractory pancreatic cancer. We expect to receive notice from the FDA within 60 days of our submission as to whether the FDA will accept our NDA for filing. In the event that the FDA does not accept our NDA for filing, we may be required to conduct additional clinical trials before resubmitting our NDA and before the FDA may accept our NDA for substantive review. If this occurs, there is likely to be a substantial delay in the approval process and it is less likely that Orathecin will be approved. You should understand this delay would have an immediate material adverse effect on our business and would likely depress the price of our stock.

Even if the FDA accepts our submission for filing, the FDA may not ultimately approve our NDA for Orathecin. The approval process may take a significant amount of time and the FDA's approval of our application will be based on its review of Orathecin's safety and efficacy. Important factors that the FDA will take into account in its review and analysis include, among other things, time to disease progression and objective tumor response as well as toxicities seen in patients who were treated with Orathecin.

Given the large scale of the Orathecin clinical program, the complexity of the clinical trials and the inherent uncertainties associated with clinical trials of such magnitude and complexity, the data and statistical analysis from these trials may not support regulatory approval or we may be required to perform additional studies before obtaining regulatory approval. For example, the design of these trials allowed patients who initially were being treated with gemcitabine or other therapies to cross over to treatment with Orathecin. At the time the trials were designed, we believed that the percentage of patients who would cross over for treatment with Orathecin would be in the range of ten percent to 20 percent of the total enrolled patients. The number of patients in our trials who actually crossed over to treatment with Orathecin significantly exceeded the number anticipated and was nearly 50 percent in two of our Phase III studies. The extent of this cross over has negatively affected the statistical analysis of the study, making it difficult to determine if the product is efficacious with respect to survival.

In May 2003, we announced data from one of our Phase III studies of Orathecin in patients with advanced pancreatic cancer, most of whom had previously failed two or more chemotherapy treatments. The study randomized 409 patients to either Orathecin or "best medical therapy." The primary study end-point was overall survival with secondary end-points, including objective tumor response and time to disease progression. We did not meet the primary end-point, although we did meet two of the secondary end-points. The two secondary end-points were independent of a cross-over effect, whereas the primary end-point was not. The released data, and the data from our other clinical trials, may not be sufficient to support regulatory approval for Orathecin, and additional trials may be required before we can obtain regulatory approval.

If, for any reason, the FDA does not accept our NDA for filing or the FDA ultimately determines not to approve our application for Orathecin, we would be unable to proceed with our current plans for commercializing Orathecin. Additionally, we might be forced to substantially scale down our operations or sell certain of our assets, and it is likely the price of our stock would decline precipitously.

Even if we receive regulatory approval of Orathecin for the treatment of patients with refractory pancreatic cancer, Orathecin may not be commercially successful.

Even if Orathecin receives regulatory approval, patients and physicians may not readily accept it, which would result in lower than projected sales and substantial harm to our business. Acceptance will be a function of Orathecin being clinically useful and demonstrating superior therapeutic effect with an acceptable side effect profile as compared to currently existing or future treatments. In addition, even if Orathecin does achieve market acceptance, we may not be able to maintain that market acceptance over time if new products are introduced that are more favorably received than Orathecin or render Orathecin obsolete.

If we do not receive regulatory approval for Dacogen, our future revenues may be limited and our business would be harmed.

We completed an interim analysis of the first 45 patients from a Phase III study, which indicated increased time to acute AML or death (median 105 days versus 92 days, p=0.036), which is the primary end-point of the study. We have also received orphan drug designation for Dacogen for the treatment of MDS in the United States and Europe, and for the treatment of sickle cell anemia in the United States. There is no assurance that our interim analysis is predictive of final results of the Phase III clinical trial, that the final results will not be materially worse, that we will not be required to conduct additional clinical trials, or that the final results will support submission of an NDA. Even if the final results support the submission of an NDA, the approval process may take a significant amount of time and we may not receive approval. If the development of Dacogen is unsuccessful for any reason, including if the final results of the Phase III study are worse than the interim analysis, our future revenues would be limited and our business would be harmed. Additionally, we might be forced to substantially scale down our operations or sell certain of our assets, and it is likely the price of our stock would decline precipitously.

Neither the fast track designations of Orathecin and Dacogen nor the accelerated approval procedures for Orathecin will necessarily lead to a faster regulatory review or approval.

If a drug is intended for the treatment of a serious or life-threatening condition for which there is no effective treatment, and the drug demonstrates the potential to address unmet medical needs for the condition, the drug sponsor may apply for FDA "fast track" designation. The fast track designation does not apply to the product alone, but instead to the combination of the product and the specific indication for which it is being studied. Under fast track provisions, the FDA is committed to working with the drug sponsor for the purpose of expediting the clinical development and evaluating the drug

safety and efficacy for that indication. A fast track designation allows the drug sponsor to submit a "rolling" NDA, whereby the FDA initiates review of sections of the application before it is complete. In some cases, a fast track designated product may also qualify for "priority" review, or review within a six-month time frame from the time an NDA is completed and filed, but this is not guaranteed.

Although we have obtained fast track designations for Orathecin for the treatment of refractory pancreatic cancer and Dacogen for the treatment of MDS, we cannot guarantee a faster development process, review or approval compared to the conventional procedures. Our drug candidates may not be granted priority review, and our fast track designation may be withdrawn by the FDA if the FDA believes that such designation is no longer supported by emerging data from our clinical development program. Our fast track designation does not guarantee that we will qualify for or be able to take advantage of the accelerated approval procedures, which are procedures that allow the FDA to approve a drug intended to treat serious or life threatening illnesses based upon a surrogate end point that is reasonably likely to predict clinical benefit. Even if the accelerated approval procedures are available to us, we may elect to use the traditional approval process for strategic and marketing reasons. If Orathecin and Dacogen are approved under the accelerated approval procedures, we will most likely be required to conduct Phase IV studies to provide confirmatory evidence that these drugs are safe, effective and provide a clinically meaningful benefit to patients. If we fail to provide such confirmatory evidence, the FDA can withdraw our approval on an expedited basis. Accelerated approval also requires that we submit all promotional labeling and advertising to the FDA for pre-approval prior to dissemination of these materials. Furthermore, if serious adverse effects are identified at any time after marketing, our approval may be rapidly revoked and we will not be allowed to continue to market the drug. If the regulatory approval for our drug candidates is delayed, or the approval is withdrawn or revoked for any reason, our business will be substantially harmed.

If we are unable to expand our regulatory approval for use of Nipent to treat additional diseases our revenues will not expand as planned.

Part of our strategy involves expanding the market opportunities for our approved drugs, including Nipent, by seeking regulatory approval and/or clinical support of their use for treatment of patients with additional diseases. We are currently marketing Nipent for the treatment of patients with hairy cell leukemia, and revenues from selling Nipent provided over 90 percent of our revenues for the past three years. We are conducting a series of clinical trials with Nipent, including Phase IV trials for CLL, NHL, cutaneous and peripheral T-cell lymphomas and Phase II/III studies for GvHD. If our Nipent clinical trials are not successful, we will not be able to seek additional regulatory approvals and we will not be able to increase our revenue from Nipent above the current level.

Risks Related to Our Financial Condition and Common Stock

We have a history of operating losses and we expect to continue to incur losses for the foreseeable future.

Since inception, we have funded our research and development activities primarily from private placements and public offerings of our securities, milestone payments and revenues generated primarily from sales of Nipent, which is marketed in the United States for the treatment of patients with hairy cell leukemia. Our substantial research and development expenditures and limited revenues have resulted in significant net losses. We have incurred cumulative losses of $286.6 million from inception through December 31, 2003, and our products have not generated sufficient revenues to support our business during that time. We expect to continue to incur substantial operating losses at least into 2005 and may never achieve profitability.

Whether we achieve profitability depends primarily on the following factors:

- our ability to obtain regulatory approval for and, if approved, to successfully commercialize Orathecin and Dacogen, and to develop and obtain regulatory approval of Nipent for indications other than hairy cell leukemia;
- our ability to bring to market other proprietary products that are advancing through our internal clinical development infrastructure;
- our ability to cost-effectively acquire technology, including in-process research and development, and other assets;
- our research and development efforts, including the timing and costs of clinical trials;
- our competition's ability to develop and bring to market competing products;
- our ability to control costs and expenses associated with manufacturing, distributing and selling our products, as well as general and administrative costs related to conducting our business;
- costs and expenses associated with entering into licensing and other collaborative agreements; and
- delays in production or inadequate commercial sales of Orathecin, Dacogen and other products, once regulatory approvals have been received.

Our products and product candidates, even if successfully developed and approved, may not generate sufficient or sustainable revenues to enable us to achieve or sustain profitability.

We will require additional funding to fully commercialize our products, and if we are unable to raise the necessary capital or to do so on acceptable terms, our planned expansion and continued survival could be harmed.

We will continue to expend substantial resources commercializing Orathecin, Dacogen and Nipent, and conducting research and development, including clinical trials for our products and product candidates. We anticipate that our capital resources following this offering will be adequate to fund operations and capital expenditures for at least the next 12 months. However, if we experience unanticipated cash requirements during this period, we could require additional funds much sooner. We may raise money by the sale of our equity securities or debt, or the exercise of outstanding warrants and stock options by the holders of such warrants and options. However, given uncertain market conditions and the volatility of our stock price, we may not be able to sell our securities in public offerings or private placements at prices and on terms that are favorable to us, if at all. Also, the dilutive effect of additional financings could adversely affect our per share results. We may also choose to obtain funding through licensing and other contractual agreements. Such arrangements may require us to relinquish our rights to our technologies, products or marketing territories, or to grant licenses on terms that are not favorable to us. If we fail to obtain adequate funding in a timely manner, or at all, we will be forced to scale back our product development activities, or be forced to cease our operations.

We substantially increased our outstanding indebtedness with the issuance of our senior convertible notes, which may make it more difficult for us to pay our debt and other obligations and which notes contain certain restrictive covenants that limit our ability to finance our operations by new debt or equity financings.

On February 26, 2003, we privately placed senior exchangeable convertible notes in the aggregate principal amount of $21.25 million with several institutional investors, which we refer to as the February Notes. Subsequently, on June 24, 2003, we privately placed senior convertible notes in the aggregate principal amount of $21.25 million with the February Note holders, which we refer to as the June Notes.

At December 31, 2003, we had outstanding indebtedness of $26.25 million, including $5.0 million from the February Notes and $21.25 million from the June Notes. The outstanding principal and interest on the February Notes was due on February 26, 2004, which we have paid subsequent to December 31, 2003 in shares of our common stock. In addition, $1.25 million of the June Notes have been converted to shares of our common stock. The remaining June Notes are due in quarterly installments on March 31, June 30, September 30 and on December 31, 2004, which we also intend to pay in shares of our common stock.

Currently, our revenues from operations will not generate sufficient cash flow to satisfy the principal payments under the Notes when they become due. We have the right to pay the principal and interest then due under the February and June Notes through the issuance of shares of common stock at a conversion price tied to the then market price. Nevertheless, our principal payments through issuance of shares of our common stock is subject to certain conditions, including limitations based on trading volumes in our common stock at such time. Therefore, we may be required to use cash to pay the principal amounts when they are due. If we decide to make payments under the February and June Notes in cash, we would deplete our financial resources, which could adversely affect our product development. If we are unable to satisfy our payment obligations under the February and June Notes, we will default, which could result in our filing for bankruptcy protection.

In addition, the holders of the February and June Notes have imposed certain restrictive covenants on us, including limits on our future indebtedness and limits on structuring equity financings with variable pricing. As a result, our obligations under the February and June Notes may or will:

- make it more difficult for us to obtain any necessary financing in the future for working capital, capital expenditures or other purposes;
- significantly increase our interest expense; and
- make us more vulnerable in the event of a downturn in our business.

Holders of the June Notes also have a right of first refusal to purchase their pro rata portion of the greater of one-third of the securities offered by us for sale in offerings or $5.0 million worth of such offered securities.

Conversion of the notes, payments on the notes in stock or redemption of the notes upon a change in control would have a dilutive effect on our stockholders.

The holders may convert the February and June Notes at any time prior to their maturity at fixed conversion prices ($4.25 for the February Notes and $6.36 for the June Notes), and we have the right, subject to certain conditions, to pay the principal and interest then due under such Notes through the issuance of shares of common stock at a conversion price tied to the then market price. If we issue shares of our common stock; (a) upon the holders' conversion of the Notes, or (b) to make payments of principal and interest due on the Notes, such issuances will be dilutive to our stockholders. In addition, if we decide to redeem the Notes in connection with a change of control, we will be required to issue to the holders certain warrants for the securities of the acquiror, which will be dilutive and may negatively affect the deal consideration the stockholders would otherwise receive.

Our equity investment in AVI exposes us to equity price risk and any impairment charge would affect our results of operations.

We are exposed to equity price risk on our equity investment in AVI. Currently we own 2,684,211 shares of AVI. In the third quarter of 2002, we recorded an other-than temporary loss of $8.2 million relating to our holding in AVI, resulting in a reduction of our cost basis in the AVI shares. Under our accounting policy, marketable equity securities are presumed to be impaired if their fair value is less than their cost basis for more than six months, absent compelling evidence to the contrary. As of

September 30, 2002, the AVI shares had been trading below our original cost basis for more than six months. Since there was no compelling evidence to the contrary, we recorded the impairment charge of $8.2 million in our results of operations. The amount of the charge was based on the difference between the market price of the shares as of September 30, 2002 and our original cost basis. The public trading prices of the AVI shares have fluctuated significantly since we purchased them and could continue to do so. If the public trading prices of these shares continue to trade below their new cost basis in future periods, we may incur additional impairment charges relating to this investment, which in turn will affect our results of operations.

In addition, in connection with the restructuring of our February Notes and the issuance of the June Notes, we issued three-year warrants to the June Note holders exercisable into up to 2,634,211 of our AVI shares at an exercise price of $5.00 per share, and we pledged the AVI shares to secure our obligation under the June Notes.

Product Development and Regulatory Risks

Before we can seek regulatory approval of any of our product candidates, we must complete clinical trials, which are expensive and have uncertain outcomes.

Most of our products are in the developmental stage and, prior to their sale, will require regulatory approval and the commitment of substantial resources. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through pre-clinical testing and clinical trials that our product candidates are safe and effective for use in humans.

We have a portfolio of cancer drugs in various stages of development, including Nipent (for indications other than hairy cell leukemia, Phase IV), Partaject busulfan (Phase I/II), inhaled Orathecin (Phase I), and we are conducting pre-clinical studies for VEGF, inhaled paclitaxel and Cremophor-free paclitaxel. In addition, we expect to commence new clinical trials from time to time in the course of our business as our product development work continues. Conducting clinical trials is a lengthy, time-consuming and expensive process and the results are inherently uncertain. We have incurred and will continue to incur substantial expense for, and we have devoted and expect to continue to devote a significant amount of time to, pre-clinical testing and clinical trials. However, regulatory authorities may not permit us to undertake any additional clinical trials for our product candidates. If we are unable to complete our clinical trials, our business will be severely harmed and the price of our stock will likely decline.

We have ongoing research and pre-clinical projects that may lead to product candidates, but we have not begun clinical trials for these projects. If we do not successfully complete our pre-clinical trials, we could not commence clinical trials as planned.

Our clinical trials may be delayed or terminated, which would prevent us from seeking necessary regulatory approvals.

Completion of clinical trials may take several years or more. The length of a clinical trial varies substantially according to the type, complexity, novelty and intended use of the product candidate. For example, our three Phase III Orathecin clinical trials lasted from 1998 through the end of 2003. The length of time and complexity of these studies make statistical analysis difficult and regulatory approval unpredictable. The commencement and rate of completion of our clinical trials may be delayed by many factors, including:

- ineffectiveness of the study compound, or perceptions by physicians that the compound is not effective for a particular indication;
- inability to manufacture sufficient quantities of compounds for use in clinical trials;

- inability to obtain FDA approval of our clinical trial protocols;
- slower than expected rate of patient recruitment;
- inability to adequately follow patients after treatment;
- difficulty in managing multiple clinical sites;
- unforeseen safety issues;
- lack of efficacy demonstrated during the clinical trials; or
- government or regulatory delays.

If we are unable to achieve a satisfactory rate of completion of our clinical trials, our business will be significantly harmed.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in compliance with regulatory requirements, if the trial results are negative, inconclusive or if they fail to demonstrate safety or efficacy.

Our clinical trials must be conducted in accordance with the FDA's regulations and are subject to continuous oversight by the FDA and institutional review boards at the medical institutions where the clinical trials are conducted. We outsource certain aspects of our research and development activities to contract research organizations, or CROs. We have agreements with these CROs for certain of our clinical programs. We and our CROs are required to comply with current GCPs, regulations and guidelines enforced by the FDA for all of our products in clinical development. The FDA enforces GCPs through periodic inspections of study sponsors, principal investigators, and study sites. If our CROs or we fail to comply with applicable GCPs, the clinical data generated in our studies may be deemed unreliable and the FDA may require us to perform additional studies before approving our applications. In addition, our clinical trials must be conducted with product candidates produced under GMPs, and may require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process.

Even if we achieve positive interim results in clinical trials, these results do not necessarily predict final results, and acceptable results in early trials may not be repeated in later trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials. Negative or inconclusive results or adverse medical events during a clinical trial could cause us to repeat or terminate a clinical trial. Our clinical trials may be suspended at any time if we or the FDA believe the patients participating in our studies are exposed to unacceptable health risks or if the FDA finds deficiencies in the conduct of these trials.

We may encounter other problems and failures in our studies that would cause us or the FDA to delay or suspend the studies. The potential failures would delay development of our product candidates, hinder our ability to conduct related pre-clinical testing and clinical trials and further delay the commencement of the regulatory approval process. Moreover, we may then be required to conduct other clinical trials for the product candidates, which would require substantial funding and time. We may be unable to obtain funding to conduct such clinical trials. The failures or perceived failures in our clinical trials would delay our product development and the regulatory approval process, damage our business prospects, make it difficult for us to establish collaboration and partnership relationships and negatively affect our reputation and competitive position in the pharmaceutical industry.

Our failure to obtain regulatory approvals to market our product candidates in foreign countries would adversely affect our anticipated revenues.

Sales of our products in foreign jurisdictions will be subject to separate regulatory requirements and marketing approvals. Approval in the United States, or in any one foreign jurisdiction, does not ensure approval in any other jurisdiction. The process of obtaining foreign approvals may result in significant delays, difficulties and expenses for us, and may require additional clinical trials. So far, we have applied through a subsidiary for regulatory approval to market mitomycin and paclitaxel in the United Kingdom and in other countries within the European Union. Although many of the regulations applicable to our products in these foreign countries are similar to the FDA's, many of these requirements also vary widely from country to country, which could delay the introduction of our products in those countries. Failure to comply with these regulatory requirements or to obtain required approvals would impair our ability to commercialize our products in foreign markets.

Nipent is currently sold in Europe. However, our role in Europe is limited to that of a supplier, and as such, we do not have a direct influence on sales at the clinical level, making their timing and magnitude difficult to predict and dependent on the efforts of our European distributors. Our revenue from supplying Nipent for European sales is insignificant, however we are currently in discussions to acquire the rights to distribute and market Nipent in Europe. Our strategy is to obtain regulatory approvals to sell our products in Europe and elsewhere, and we intend to contract with third-party licensees or distributors for sales outside the United States. Delays in obtaining regulatory approval from foreign jurisdictions will impair the commercialization of our products and would delay anticipated revenues.

Even if we obtain regulatory approval, we will continue to be subject to extensive government regulation that may cause us to delay the introduction of our products or withdraw our products from the market.

Even if regulatory approval of our products is obtained, later discovery of previously unknown problems may result in restrictions of a product, including withdrawal of that product from the market. Further, governmental approval may subject us to ongoing requirements for post-marketing studies. For example, despite receipt of governmental approval, the facilities of our third-party manufacturers are still subject to unannounced inspections by the FDA and must continue to comply with GMPs and other regulations. These regulations govern all areas of production, record keeping, personnel and quality control.

In the past, our third-party manufacturers have experienced delayed FDA approval, which adversely affected our ability to supply Nipent in 2002. If we or our third-party manufacturers fail to comply with any of the manufacturing regulations, we may be subject to, among other things, product seizures, recalls, fines, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecution.

Physicians may prescribe drugs for uses that are not described in a product's labeling for uses that differ from those tested by us and approved by the FDA. While such "off-label" uses are common and the FDA does not regulate physicians' choice of treatments, the FDA does restrict a manufacturer's communications on the subject of off-label use. Companies cannot actively promote FDA-approved drugs for off-label uses, but they may disseminate to physicians articles published in peer-reviewed journals. To the extent allowed by law, we intend to disseminate peer-reviewed articles on our products to our physician customers. If, however, our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings and/or enforcement action by the FDA. For example, in November 2002 we issued a press release announcing our receipt of FDA approval to market Mitozytrex. In March 2003, the FDA issued a "Talk Paper" regarding this press release, taking the position that we made certain unsupported claims about the drug and did not disclose the serious side effects such as suppression of bone marrow activity. We revised our internal procedures to help

ensure our promotional activities and public disclosure will meet regulatory requirements. Nonetheless, any warning or enforcement actions by the FDA could harm our reputation in the market, result in significant fines or have other results that would harm our business.

The continuing efforts of government and third-party payers to contain or reduce the costs of healthcare may adversely affect our revenues.

Sales of our products depend in part upon the availability of reimbursement from third-party payers, such as health administration authorities like Medicare/Medicaid, managed care providers and private health insurers. Third-party payers are increasingly challenging the price and examining the cost effectiveness of medical products and services, which may effectively limit physicians' ability to select products and procedures.

In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. For example, currently Medicare does not reimburse self-administered products, which could cover some of our product candidates. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in a particular product. In addition, we believe government agencies will continue to propose and pass legislation designed to reduce the cost of healthcare, which could further limit reimbursement for pharmaceuticals, and we anticipate that there will continue to be proposals in the United States to implement government control over the pricing or profitability of prescription pharmaceuticals, as is currently the case in many foreign markets. If our current and proposed products are not considered cost-effective, reimbursement to the consumer may not be available or be sufficient to allow us to sell products on a competitive basis. The failure of the government and third-party payers to provide adequate coverage and reimbursement rates for our product candidates could adversely affect the market acceptance of our products, our competitive position and our financial performance.

If we are unable to comply with environmental laws and regulations, our business may be harmed.

We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We currently maintain a supply of biohazardous materials at our facilities. We believe our safety procedures for these materials comply with all applicable environmental laws and regulations, and we carry insurance coverage we believe is adequate for the size of our business. However, we cannot entirely eliminate the risk of accidental contamination or injury from these materials. If an accident or environmental discharge occurs, we could be held liable for any resulting damages, which could exceed our insurance coverage and financial resources.

We currently outsource certain of our research and development programs involving the controlled use of biohazardous materials. We believe our collaborators have in place safety procedures for these materials that comply with governmental standards. Nevertheless, if an accident does occur, our research and product development will be negatively affected.

Additional Risks Associated with Our Business

If the third-party manufacturers upon whom we rely fail to produce our products in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the delivery of, or be unable to meet demand for, our products.

Because we have no manufacturing facilities, we rely on third parties for manufacturing activities related to all of our products. As we develop new products and increase sales of our existing products, we must establish and maintain relationships with manufacturers to produce and package sufficient

supplies of our finished pharmaceutical products, including Orathecin, Dacogen and Nipent. Reliance on third party manufacturing presents the following risks:

- delays in scale-up to quantities needed for multiple clinical trials, or failure to (a) manufacture such quantities to our specifications or (b) deliver such quantities on the dates we require, which could cause delay or suspension of clinical trials, regulatory submissions and commercialization of our products;
- inability to fulfill our commercial needs if market demand for our products increases suddenly, which would require us to seek new manufacturing arrangements and may result in substantial delays in meeting market demand;
- potential relinquishment or sharing of intellectual property rights to any improvements in the manufacturing processes or new manufacturing processes for our products; and
- unannounced ongoing inspections by the FDA and corresponding state agencies for compliance with GMPs, regulations and foreign standards, and failure to comply with any of these regulations and standards may subject us to, among other things, product seizures, recalls, fines, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecution.

Any of these factors could delay clinical trials or commercialization of our product candidates under development, interfere with current sales and entail higher costs. For example, a failed production batch of Nipent in the second quarter of 2003 affected our ability to supply Nipent and adversely affected our sales.

Currently we store the majority of the unpurified, bulk form of Nipent at the manufacturer's location. Improper storage, fire, natural disaster, theft or other conditions at this location may lead to the loss or destruction of the bulk concentrate. Even if the manufacturer's and our insurance coverage is adequate, such event would inevitably cause delays in distribution and sales of our products and harm our operating results.

Our business may be harmed if the manufacture of our products is interrupted or discontinued.

We may be unable to maintain our relationships with our third-party manufacturers. If we need to replace or seek new manufacturing arrangements, we may have difficulty locating and entering into arrangements with qualified contract manufacturers on acceptable terms, if at all. We are aware of only a limited number of companies on a worldwide basis who operate manufacturing facilities in which our products can be manufactured to our specifications and in compliance with GMPs. It could take several months, or significantly longer, for a new contract manufacturing facility to obtain FDA approval and to develop substantially equivalent processes for the production of our products. We may not be able to contract with any of these companies on acceptable terms, if at all. For example, the company that had been purifying Nipent filed for bankruptcy in mid 2001. Shortly thereafter we contracted with a new manufacturer for the purification of Nipent, and that manufacturer was qualified by the FDA by May 2002. We experienced unusually low inventory levels during the first quarter of 2002, while we were waiting for the new company to be qualified. Nipent is currently being purified at Hauser Technical Services, Inc. Hauser's parent company and its wholly-owned subsidiaries filed for reorganization under Chapter 11 in April 2003. However, we do not believe that this filing will have any significant impact on our supply agreement and our ability to manufacture Nipent, although there can be no assurance in this regard.

If our suppliers cannot provide the components we require, our product sales and revenue could be harmed.

We rely on third-party suppliers to provide us with numerous components used in our products under development, including Orathecin and Dacogen. Relying on third-party suppliers makes us

vulnerable to component failures and interruptions in supply, either of which could impair our ability to conduct clinical trials or to ship our products to our customers on a timely basis. Using third-party suppliers makes it difficult and sometimes impossible for us to maintain quality control, manage inventory and production schedules and control production costs. Vendor lead times to supply us with ordered components vary significantly and can exceed six months or more. Both now and as we expand our need for manufacturing capacity, we cannot be sure that our suppliers will furnish us with required components when we need them. These factors could make it difficult for us to effectively and efficiently manufacture our products, and could adversely impact our clinical trials, product development and sales of our products.

Some suppliers are our only source for a particular component, which makes us vulnerable to cost increases and supply interruptions. We generally rely on one manufacturer for each product. We rely on one manufacturer for Nipent, a sole source supplier for the processing of pentostatin, which is used in the manufacturing of Nipent, and a sole source supplier for the ingredient used in the purification of pentostatin. We also rely on sole source suppliers for mitomycin products and Surface Safe.

Vendors may decide to limit or eliminate sales of certain products to the medical industry due to product liability or other concerns. For example, one component used in the purification of pentostatin is no longer commercially available. In the event one of our sole source suppliers decides not to manufacture the component, goes out of business, or decides to cut off our supply, we may be unable to locate replacement supply sources, or the sources that we may locate may not provide us with similar reliability or pricing and our business could suffer. If we cannot obtain a necessary component, we may need to find, test and obtain regulatory approval for a replacement component, produce the component or redesign the related product, which would cause significant delay and could increase our manufacturing costs. Any of these events could adversely impact our sales and results of operations.

We have limited sales and marketing capabilities and may not be able to successfully commercialize our products.

We currently have limited sales and marketing resources. Although we have approximately 24 sales and marketing personnel focusing on the sale of our products to hospitals and hospital buying groups, we must expand our sales and marketing organization to support commercialization of our new products. Building up our sales capabilities will require significant expenditures. We may not succeed in expanding and enhancing our sales and marketing capabilities or have sufficient resources to do so. If we do develop such capabilities, we will compete with other companies that have experienced and well-funded sales and marketing operations. We may not be able to upgrade our in-house sales expertise which may limit our ability to gain market acceptance for our products worldwide and generate revenues. If we fail to establish successful sales and marketing capabilities, we will not be able to market or sell our products effectively and our business, financial condition and results of operations will be materially and adversely affected.

We intend to enter into strategic partnerships for the commercialization of our products outside of the United States. However, we may not be able to negotiate acceptable arrangements with partners, if at all. Moreover, such arrangements may involve sharing of profits from sales, requirements to relinquish certain of our rights to our products or marketing territories and impositions of other limitations on our operations.

If we are not able to maintain and successfully establish new collaborative and licensing arrangements with third parties, our product development and business will be harmed.

Our business model is based on establishing collaborative relationships with other parties both to license compounds upon which our products and technologies are based and to manufacture our products or our collaborators' products. It is critical that we gain access to compounds and technologies

to license for further development. For example, we licensed the exclusive worldwide royalty-bearing rights to Orathecin from Stehlin. Due to the expense of the drug approval process we must have relationships with established pharmaceutical companies to offset some of our development costs in exchange for a combination of development, marketing and distribution rights.

From time to time we enter into discussions with various companies regarding the establishment of new collaborations. If we are not successful in establishing new partners for our product candidates, we may not be able to pursue further development of such product candidates and/or may have to reduce or cease our current development programs, which would materially harm our business. Even if we are successful in establishing new collaborations, they are subject to numerous risks and uncertainties including:

- our ability to negotiate acceptable collaborative arrangements;
- freedom of our collaborative partners to pursue alternative technologies either on their own or with others, including our competitors, for the diseases targeted by our programs and products;
- the potential failure of our partners to fulfill their contractual obligations or their decision to terminate our relationships, in which event we may be required to seek other partners, or expend substantial resources to pursue these activities independently; and
- our ability to manage, interact and coordinate our timelines and objectives with our collaborative partners may not be successful.

In addition, our collaborators may undergo business combinations, which could have the effect of making a collaboration with us less attractive to them for a number of reasons. For example, if an existing collaborator purchases a company that is one of our competitors, that company may be less willing to continue its collaboration with us. A company that has a strategy of purchasing companies with attractive technologies might have less incentive to enter into a collaboration agreement with us. Moreover, disputes may arise with respect to the ownership of rights to any technology or products developed with any current or future collaborator. Lengthy negotiations with potential collaborators or disagreements between us and our collaborators may lead to delays in or termination of the research, development or commercialization of product candidates or result in time consuming and expensive litigation or arbitration.

Our collaborative relationships with third parties could cause us to expend significant funds on development costs with no assurance of financial return.

From time to time we enter into collaborative relationships with third parties to co-develop and market products. For example, we entered into an agreement with Peregrine Pharmaceuticals in February 2001, pursuant to which we licensed a drug-targeting technology known as Vascular Targeting Agent, which is a proprietary platform designed to specifically target a tumor's blood supply and subsequently destroy the tumor with various attached therapeutic agents. The licensed technology is specifically related to VEGF. Under the agreement, we made an up-front equity investment in Peregrine of $600,000 and will be obligated to make subsequent milestone payments that could ultimately total $8.25 million. In addition, we will pay royalties to Peregrine based on the net revenues of any drugs we commercialize using the VEGF technology.

These relationships require substantial financial commitments from us, and at the same time the product developments are subject to the same regulatory requirements, risks and uncertainties associated with the development of our other product candidates. The compounds that are the subject of these collaborative agreements may prove to be ineffective, may fail to receive regulatory approvals, may be unprotectable by patents or other intellectual property rights, or may not be otherwise commercially viable. If these collaborative relationships are not successful, our product developments

will be adversely affected, and our investments and efforts devoted to the product developments will be wasted.

The termination of our Orathecin-related agreements with Abbott may negatively impact our business and collaborative relationships.

In December 1999, we entered into agreements with Abbott Laboratories pursuant to which Abbott would market and distribute Orathecin, provide significant milestone payments and invest in shares of our common stock. The Orathecin related agreements with Abbott were terminated by the parties in March 2002. As a result of the termination of the agreements, we no longer have the opportunity to receive future milestone payments, equity investments and royalty payments from Abbott (in the aggregate amount of up to $52.5 million). Moreover, we no longer have access to Abbott's worldwide sales capability. The termination of the agreements may have been perceived negatively by other potential partners and may negatively impact our ability to establish future collaboration relationships with other pharmaceutical companies.

Our ability to protect our intellectual property rights will be critically important to the success of our business, and we may not be able to protect these rights in the United States or abroad.

The success of our operations depends in part on our ability to obtain patents, protect trade secrets, operate without infringing the proprietary rights of others and enforce our proprietary rights against accused infringers.

We actively pursue a policy of seeking patent protection when applicable for our proprietary products and technologies, whether they are developed in-house or acquired from third parties. We attempt to protect our intellectual property position by filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. To date, we have acquired licenses to or assignments of over 40 U.S. patents covering various aspects of our proprietary drugs and technologies, including 34 patents for various aspects of Orathecin and related products, five patents under our Nipent product portfolio, although none covers the use of Nipent for the treatment of patients with hairy cell leukemia, five patents for our paclitaxel related products, one patent for Dacogen used in combination with an anti-neoplastic agent for the treatment of cancer, and two patents for our Surface Safe product. These issued United States patents will begin to expire in October 2012. We have been granted patents and have received patent licenses relating to our proprietary formulation technology, non-oncology and Partaject technologies, among which at least five patents are issued or licensed to us. In addition, we are prosecuting a number of patent applications for drug candidates that we are not actively developing at this time.

We also have patents, licenses to patents and pending patent applications in Europe, Australia, Japan, Canada, Mexico and New Zealand, among other countries. In addition, we have patent applications pending in China, Hungary and Israel. Limitations on patent protection, and the differences in what constitutes patentable subject matter, may limit the protection we have on patents issued or licensed to us in these countries. In addition, laws of foreign countries may not protect our intellectual property to the same extent as would laws in the United States. To minimize our costs and expenses and to maintain effective protection, we focus our patent and licensing activities within the European Union, Canada and Japan. In determining whether or not to seek patent protection or to license any patent in a foreign country, we weigh the relevant costs and benefits, and consider, among other things, the market potential and profitability, the scope of patent protection afforded by the law of the jurisdiction and its enforceability, and the nature of terms with any potential licensees. Failure to obtain adequate patent protection for our proprietary drugs and technology would impair our ability to be commercially competitive in these markets.

The pharmaceutical industry is characterized by a large number of patent filings involving complex legal and factual questions, and therefore we cannot predict with certainty whether our patents will be enforced effectively. Competitors may have filed applications for, or been issued patents on, products or processes that compete with or are similar to ours. We may not be aware of all of the patents potentially adverse to our interests which may have been issued to others. In addition, third parties may challenge, invalidate or circumvent any of our patents. Thus, any patents that we own or license from third parties may not provide adequate protection against competitors, if at all. Our pending patent applications and those we may file in the future, or those we may license from third parties, may not result in patents being issued with adequate claim scope, if at all.

In addition to pursuing patent protection in appropriate instances, we also rely on trade secret protection or regulatory marketing exclusivity for unpatented proprietary technology. However, trade secrets are difficult to protect. Our trade secrets or those of our collaborators may become known or may be independently discovered by others.

In the pharmaceutical industry there has been, and we believe that there will continue to be, significant litigation regarding patent and other intellectual property rights. Claims may be brought against us in the future based on patents held by others. These persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the affected product. If we become involved in litigation, it could consume a substantial portion of our resources, regardless of the outcome of the litigation. If a lawsuit against us is successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product. We cannot assure you that we would prevail in a lawsuit filed against us or that we could obtain any licenses required under any patents on acceptable terms, if at all.

Our proprietary products are dependent upon compliance with numerous licenses and agreements. These licenses and agreements require us to make royalty and other payments, reasonably exploit the underlying technology of the applicable patents, and comply with regulatory filings. If we fail to comply with these licenses and agreements, we could lose the underlying rights to one or more of these potential products, which would adversely affect our product development and harm our business.

If we fail to compete effectively against other pharmaceutical companies, our business will suffer.

The pharmaceutical industry in general and the oncology sector in particular is highly competitive and subject to significant and rapid technological change. Our competitors and probable competitors include companies such as Aventis SG, Berlex Laboratories, Bristol-Myers Squibb Company, Eli Lilly & Co., GlaxoSmithKline, Novartis AG, Pfizer, Pharmion Corp. and others.

Many of our competitors and research institutions are addressing the same diseases and disease indications and working on products to treat such diseases as we are, and have substantially greater financial, research and development, manufacturing and marketing experience and resources than we do. Some of our competitors have received regulatory approval of, or are developing or testing product candidates that compete directly with, our product candidates. For example, while we received orphan drug status for Orathecin and there is currently no competitor in the oral delivery market for the treatment of pancreatic cancer, there are approved drugs for the treatment of pancreatic cancer, including gemcitabine by Eli Lilly. In addition, Berlex Laboratories' fludarabine competes with Nipent in the leukemia market, and Dacogen faces potential competition from Pharmion's azacitidine, if approved by the FDA.

Many of these competitors have significantly greater experience than we do in developing products, undertaking pre-clinical testing and clinical trials, obtaining FDA and other regulatory approvals, and manufacturing and marketing products. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or commercializing products before we do. If we commence sales

of our product candidates, we will be competing against companies with greater marketing expertise and manufacturing capabilities, areas in which we have limited or no experience.

We also face intense competition from other companies for collaborative relationships, for establishing relationships with academic and research institutions, and for licenses to proprietary technology.

Our competitive positions in our generic drugs are uncertain and subject to risks. The market for generic drugs, including the pricing for generic drugs, is extremely competitive. As a result, unless our generic drugs are the first or among the initial few to launch, there is a high risk that our products would not gain meaningful market share, or we would not be able to maintain our price and continue the product line. Moreover, marketing of generic drugs is also subject to regulatory approval, and if we were not able to obtain such approval before our competitors, we would lose our competitive advantage. Failure to maintain our competitive position could have a material adverse effect on our business and results of operations.

The pharmaceutical industry in general and the oncology sector in particular is subject to significant and rapid technological change. Developments by competitors may render our product candidates or technologies obsolete or non-competitive.

Our competitors may succeed in developing technologies or products that are more effective than ours. Additionally, our products that are under patent protection face intense competition from competitors' proprietary products. This competition may increase as new products enter the market.

A number of our competitors have substantially more capital, research and development, regulatory, manufacturing, marketing, human and other resources and experience than we have. As a result, our competitors may:

- develop products that are more effective or less costly than any of our current or future products or that render our products obsolete;
- produce and market their products more successfully than we do;
- establish superior proprietary positions; or
- obtain FDA approval for labeling claims that are more favorable than those for our products.

We will also face increasing competition from lower-cost generic products after patents on our proprietary products expire. Loss of patent protection typically leads to a rapid decline in sales for that product and could affect our future results. As new products enter the market, our products may become obsolete or our competitors' products may be more effective or more effectively marketed and sold than our products. Technological advances, competitive forces and loss of intellectual property protection rights for our products may render our products obsolete.

We are developing products based upon compounds that may be covered by patents held by third parties that are expected to expire or already expired. These compounds may also be the subject of method, formulation, and manufacturing process patents held by third parties. If these patents do not expire as anticipated or are expanded in scope, we will not be able to develop our products as planned.

We developed, or are in the process of developing, and are planning to market several generic and proprietary formulation products based on existing compounds. Specifically, with respect to our generic products, we received approval of an ANDA, for our generic mitomycin for solid tumors, and daunorubicin for a variety of acute leukemias, and have filed an ANDA for our generic paclitaxel.

Our proprietary formulation technology is a platform technology that employs the use of an inert chemical excipient, cyclodextrin, combined with a drug. Most anti-cancer drugs are cytotoxic, and most

must be administered intravenously. If a vein is missed on injection, the drug can leak to surrounding tissue, causing ulceration that sometimes requires plastic surgery to correct. Our proprietary formulation technology is designed to "shield" the drug from the injection site, thus providing the patient protection from tissue ulceration. This technology may increase the relative solubility of hard-to-dissolve anti-cancer drugs, hence increasing its stability or shelf life. However, each of these benefits must be supported by appropriate data and approved by the FDA before we can make any claim in this regard. Our first product utilizing our proprietary formulation technology, a formulation of generic mitomycin, was approved by the FDA in November 2002 as Mitozytrex (mitomycin for injection) for use in the therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed. We cannot promote Mitozytrex as providing any injection site ulceration protection, nor can we promote any increased stability, solubility or shelf life extension, as compared to generic mitomycin. We would be required to develop and submit additional data to the FDA and receive FDA approval before we could make these claims.

Through December 31, 2003, we have spent approximately $6.4 million on developing and marketing our generic and proprietary formulation products. We have completed our pre-commercial investment in developing Mitozytrex, and as of now we have not committed to an internal budget for additional proprietary formulation development programs. In addition, we have no further generic drug development commitments, as we are focusing on developing our proprietary drug candidates.

We do not hold any intellectual property rights as to the underlying compounds on which our generic or proprietary formulation products are based. We may in the future evaluate the generic drug market and develop additional generic or proprietary products based on these compounds, which may also be the subject of method, formulation and manufacturing process patents held by third parties. Our development of generic or proprietary products may also take place prior to, but in anticipation of, the expected expiration of existing patent protection for drugs developed by third parties. However, if existing patent protection on such products is otherwise maintained, extended or expanded, it is unlikely that we will be able to market our own generic or proprietary formulation products without obtaining a license from the patent owner, which may not be available on commercially acceptable terms, if at all.

We may be subject to product liability lawsuits and our insurance may be inadequate to cover damages.

Clinical trials and commercial use of our current and potential products may expose us to liability claims from the use or sale of these products. Consumers, healthcare providers, pharmaceutical companies and others selling such products might make claims of this kind. We may experience financial losses in the future due to product liability claims. We have obtained limited product liability insurance coverage for our products and clinical trials, under which the coverage limits are $10.0 million per occurrence and $10.0 million in the aggregate. We do not know whether this coverage will be adequate to protect us in the event of a claim. We may not be able to obtain or maintain insurance coverage in the future at a reasonable cost or in sufficient amounts to protect us against losses. If third parties bring a successful product liability claim or series of claims against us for uninsured liabilities or in excess of insured liabilities, we may not have sufficient financial resources to complete development or commercialization of any of our product candidates and our business and results of operations will be adversely affected.

We are transitioning new members of the management team into the Company and if the transition is not smooth, our business will be disrupted. Further, if we are unable to attract and retain additional, highly skilled personnel required for the expansion of our activities, our business will suffer.

We have recently undergone changes in our senior management. Dr. Joseph Rubinfeld, who served as our president and chief executive officer since 1991, retired from this position on December 31,

2003, although he remains on our board of directors and serves as our chief scientist. Dr. James Manuso, who has served on our board of directors since 2001, was appointed to the position of president and chief executive officer effective January 1, 2004. In addition, Edward Jacobs was recently appointed to the position of chief operating officer, and Michael Molkentin was appointed to fill the position of chief financial officer. Also, Craig S. Rosenfeld recently resigned from his position as our senior vice president, chief scientific officer. Changes in our senior management may be disruptive to our business and may adversely affect our operations.

Further, our success is dependent on key personnel, including members of our senior management and scientific staff. If any of our executive officers decides to leave and we cannot locate a qualified replacement in time to allow a smooth transition, our business operation may be adversely affected. To successfully expand our operations, we will need to attract and retain additional highly skilled individuals, particularly in the areas of sales, marketing, clinical administration, manufacturing and finance. We compete with other companies for the services of existing and potential employees, however to the extent these employees favor larger, more established employers, we may be at a disadvantage.

Earthquake or other natural or man-made disasters and business interruptions could adversely affect our business.

Our operations are vulnerable to interruption by fire, power loss, floods, telecommunications failure and other events beyond our control. In addition, our operations are susceptible to disruption as a result of natural disasters such as earthquakes. So far we have never experienced any significant disruption of our operations as a result of earthquakes or other natural disasters. Although we have a contingency recovery plan, any significant business interruption could cause delays in our drug development and sales and harm our business.

Provisions in our certificate of incorporation, bylaws and applicable Delaware law may prevent or discourage third parties or stockholders from attempting to replace our management.

Anti-takeover provisions of our certificate of incorporation and bylaws make it more difficult for a third party to acquire us, even if doing so would be beneficial to our stockholders. These provisions include:

- authorization of the issuance of up to 2,000,000 shares of our preferred stock;
- elimination of cumulative voting; and
- elimination of stockholder action by written consent.

Our bylaws establish procedures, including notice procedures, with regard to the nomination, other than by or at the direction of our board of directors, of candidates for election as directors or for stockholder proposals to be submitted at stockholder meetings.

We are also subject to Section 203 of the Delaware General Corporation Law, an anti-takeover provision. In general, Section 203 of the Delaware General Corporation Law prevents a stockholder owning 15 percent or more of a corporation's outstanding voting stock from engaging in business combinations with a Delaware corporation for three years following the date the stockholder acquired 15 percent or more of a corporation's outstanding voting stock. This restriction is subject to exceptions, including the approval of the board of directors and of the holders of at least two-thirds of the outstanding shares of voting stock not owned by the interested stockholder.

We believe that the benefits of increased protection of our potential ability to negotiate with the proponents of unfriendly or unsolicited proposals to acquire or restructure us outweigh the disadvantages of discouraging those proposals because, among other things, negotiation of those

proposals could result in an improvement of their terms. Nevertheless, these provisions are expected to discourage different types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of our company to first negotiate with us, and may have the effect of preventing or discouraging third parties or stockholders from attempting to replace our management.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Due to the short-term nature of our interest bearing assets, which consist primarily of certificates of deposit, United States corporate obligations, and United States government obligations, we believe that our exposure to interest rate market risk would not significantly affect our operations.

Our investment policy is to manage our marketable securities portfolio to preserve principal and liquidity while maximizing the return on the investment portfolio. Our marketable securities portfolio is primarily invested in corporate debt securities with an average maturity of under one year and a minimum investment grade rating of A or A-1 or better to minimize credit risk. Although changes in interest rates may affect the fair value of the marketable securities portfolio and cause unrealized gains or losses, such gains or losses would not be realized unless the investments were to be sold prior to maturity.

As part of our June 2003 convertible debt transaction, we issued to the note holders warrants to purchase 2,634,211 shares of common stock of AVI at $5.00 per share. These warrants are considered a derivative and were valued on the balance sheet at $10.1 million using the Black-Scholes method on June 24, 2003. On December 31, 2003, the value of the derivative had declined to $5.5 million. As the fair value of the common stock of AVI has fluctuated significantly in the past two years, the valuation of the derivative may have a significant impact on our results of operations.

We operate primarily in the United States and all product sales are denominated in U.S. dollars. Accordingly, we do not have any exposure to foreign currency rate fluctuations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

All information required by this item is included on pages F-1 to F-26 in Item 15 of Part IV of this Report and is incorporated into this item by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Our chief executive officer and our chief financial officer, after evaluating our "disclosure controls and procedures" (as defined in Securities Exchange Act of 1934, or the Exchange Act, Rules 13a-14(c) and 15-d-14(c)) as of a date (the "Evaluation Date") within 90 days before the filing date of this Annual Report on Form 10-K, have concluded that as of the Evaluation Date, our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

Subsequent to the Evaluation Date, there were no significant changes in our internal controls or in other factors that could significantly affect our disclosure controls and procedures, nor were there any significant deficiencies or material weaknesses in our internal controls. As a result, no corrective actions were required or undertaken.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

Information regarding our Board of Directors is incorporated by reference to the section entitled "Election of Directors" appearing in our definitive Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission by April 15, 2004 (the "Proxy Statement").

The names of our executive officers and their ages, titles and biographies as of February 26, 2004 are set forth below.

Executive Officers

Name	Age	Position
James S. J. Manuso, Ph.D.	55	President, Chief Executive Officer and Director
Edward L. Jacobs	57	Chief Operating Officer
Audrey Jakubowski, Ph.D.	61	Senior Vice President, Regulatory Affairs
Karl L. Mettinger, M.D., Ph.D.	60	Senior Vice President, Chief Medical Officer
Michael Molkentin	49	Chief Financial Officer

James S.J. Manuso, Ph.D., has served as our president and chief executive officer since January 1, 2004, as our chief executive officer-elect since September 2003 and as a director since February 2001. Dr. Manuso is co-founder and immediate past president and chief executive officer of Galenica Pharmaceuticals, Inc. Immediately prior to this appointment, he was president of Manuso, Alexander & Associates, Inc., management consultants and financial advisors to pharmaceutical and biotechnology companies since 1992. Dr. Manuso co-founded and was general partner of PrimeTech Partners, a venture management partnership that developed biotechnology companies, from 1998 to 2002. He serves on the boards of privately-held companies, including Quark Biotech, Inc., Galenica, Symbiontics, Inc., and KineMed, Inc. Previously, he served on the board of Inflazyme Pharmaceuticals, Inc. Dr. Manuso earned an A.B. with Honors in Economics and Chemistry from New York University, a Ph.D. in Experimental Psychophysiology from the Graduate Faculty of The New School University, where he was a New School Scholar, a Certificate in Health Systems Management from Harvard Business School, and an Executive M.B.A. from Columbia Business School where he was an Equitable Companies Scholar. Dr. Manuso is the author of over 30 chapters, articles and books on topics including health care systems general management and biotech company development. He has taught at Columbia, Georgetown, Waseda University (Japan) and elsewhere and he has delivered invited addresses to the American Medical Association, the Biotechnology Industry Association, the Securities Industry Association and many other professional associations.

Edward L. Jacobs rejoined us in October 2001 as chief business officer and chief financial officer, and in October 2003 became our chief operating officer. From February 2001 through September 2001, he served as president and chief executive officer of ETEX Corporation. He originally came to us as executive vice president, commercial operations in March 1999 and served in that position until January 2001. Prior to joining us in 1999 Mr. Jacobs served as senior vice president, commercial operations at Sequus Pharmaceuticals, Inc. from November 1997 to March 1999. Between January 1995 and November 1997, Mr. Jacobs served as president and chief executive officer of Trilex Pharmaceuticals Inc., now Titan Pharmaceuticals. Prior to his association with Trilex, Mr. Jacobs served in a variety of senior management positions with pharmaceutical companies, including chief executive at Transplant Therapeutics Inc., vice president and general manager of Syncor International Inc., vice president at NEORX Corporation, business director of Pharmacia Corp., The Upjohn Company (Adria Labs, Inc.) and Johnson & Johnson (McNeil). Mr. Jacobs received a B.A. in Political Science/ Journalism from California State University at Northridge.

Audrey Jakubowski, Ph.D., joined us as vice president, regulatory affairs in August 1998 and served in that capacity until October 2003 when she became senior vice president, regulatory affairs. In January 2004, she was also given responsibility for quality assurance. Prior to joining us, Dr. Jakubowski was vice president, regulatory affairs and quality at Systemix, Inc. from June 1996 to July 1998. From October 1989 through June 1996, Dr. Jakubowski was executive director and then vice president of worldwide regulatory affairs for The DuPont Merck Pharmaceutical Company. From November 1979 through October 1989, Dr. Jakubowski was first director of regulatory affairs, dermatology products at Westwood Pharmaceuticals, followed by director of international regulatory affairs, R&D products for Bristol Myers' research and development division. Prior to that, Dr. Jakubowski completed post-doctoral fellowships in molecular biology at the Roswell Park Memorial Institute and clinical endocrinology at Buffalo Children's Hospital. Dr. Jakubowski received her Ph.D. in physical chemistry at SUNY Buffalo and her B.A. at Seton Hall College.

Karl L. Mettinger, M.D., Ph.D., joined us in August 2000 as senior vice president and chief medical officer. Prior to joining us, Dr. Mettinger was at IVAX Corporation/Baker Norton Pharmaceuticals for 11 years, where he served in a number of senior management positions, including executive director, clinical research; senior director, clinical research; and medical director. Prior to IVAX, Dr. Mettinger was deputy general manager and medical director at KABI Cardiovascular/Hematology (currently Pharmacia). He was a physician at the Karolinska Hospital from 1974 to 1985, where he became board certified in 1978, and was an associate professor there from 1983 to 1989. Dr. Mettinger obtained his medical degree at the University of Lund, Sweden in 1973, his ECFMG certification in 1974, and his doctorate in the field of Hematology at the Karolinska Institute in 1982.

Michael Molkentin joined us as chief financial officer and corporate secretary in October 2003. Prior to joining us, Mr. Molkentin served as interim chief financial officer at Aradigm Corporation from May 2000 to September 2002. From January 1995 to April 2000, Mr. Molkentin served as division controller for Thermo Finnigan Corporation, a subsidiary of Thermo Electron. Mr. Molkentin served in a variety of financial management positions with technology companies, including field controller of Vanstar Corporation, controller of Republic Telcom Systems, Inc. and corporate controller of Computer Automation, Inc. Mr. Molkentin is a CPA and received a B.B.A. in accounting from Bernard M. Baruch College in New York City, New York.

Audit Committee Financial Expert

Information regarding the financial expert(s) on the Audit Committee is incorporated by reference to the Proxy Statement.

Audit Committee

Information regarding the Audit Committee is incorporated by reference to the Proxy Statement.

Code of Ethics

Information regarding the Code of Ethics is incorporated by reference to the Proxy Statement.

Corporate Governance Guidelines

Information regarding Corporate Governance Guidelines is incorporated by reference to the Proxy Statement.

Section 16(a) Beneficial Ownership Reporting Compliance

Information regarding Section 16(a) beneficial ownership reporting compliance is set forth under "Voting Securities of Principal Stockholders and Management" in the Proxy Statement, which information is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

Information regarding executive compensation is incorporated by reference to the information set forth under the caption "Executive Compensation" in the Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

Information regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth under the caption "Voting Securities of Principal Stockholders and Management" in the Proxy Statement. Information regarding our Equity Compensation Plans may be found in Part II, Item 5 of this report.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

Information regarding certain relationships and related transactions is incorporated by reference to the information set forth under the caption "Certain Transactions" in the Proxy Statement. Certain of our relationships and related transactions are addressed in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this report.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

Information regarding principal auditor fees and services is set forth under "Principal Accounting Fees and Services" in the Proxy Statement, which information is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

(a) The following documents are filed as part of this report:

1. *All Financial Statements:*

The following financial statements and the Report of Ernst & Young LLP, Independent Auditors, are included in Part IV of this Report on the pages indicated:

2. *Financial Statement Schedules:*

All schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or the notes thereto.

3. *Exhibits:*

Exhibit Number	Description of Document
(f)3.1	Amended and Restated Certificate of Incorporation of the Registrant.
(ff)3.2	Bylaws of the Registrant, as amended and restated through May 30, 2001
(m)4.1	Specimen Common Stock Certificate.
(a)4.2	Form of Representative's Warrant.
(a)4.3	Form of Warrant Agreement dated March 11, 1996 (including form of Common Stock Purchase Warrant).
(l)10.1	Form of Indemnification Agreement between the Registrant and each of its directors and officers.
(cc)(s)10.2	1993 Stock Option Plan (as amended through July 11, 2000).
(i)(s)10.3	Forms of stock option agreements under the 1993 Stock Option Plan.
(n)(s)10.4	1996 Directors' Stock Option Plan, as amended effective February 7, 2001.
(c)(s)10.5	Employees and Consultants Stock Option Agreement/Plan.
(n)(s)10.6	1998 Employee Stock Purchase Plan, as amended February 7, 2001.
(b)(q)10.7	Patent License and Royalty Agreement dated August 30, 1993 between the Registrant and The Jackson Laboratory.
(b)(q)10.8	Worldwide License Agreement dated March 1, 1994 between the Registrant and Janssen Biotech, N.V.
(b)(q)10.9	Patent License Agreement dated March 1, 1994 between the Registrant and Cyclex Inc.
(b)(q)10.10	Patent License and Royalty Agreement dated November 15, 1993 between the Registrant and The Long Island Jewish Medical Center.
(b)(q)10.11	License Agreement dated February 1, 1995 between the Registrant and Pharmos Corporation.
(ll)(s)10.12	2003 Stock Plan
(s)10.13	Employment, Confidential Information, Invention Assignment and Arbitration Agreement dated January 1, 2004 between Registrant and Joseph Rubinfeld.

Exhibit Number	Description of Document
(s)10.14	Executive Employment and Confidential Information and Invention Assignment Agreement dated January 1, 2004 between Registrant and James Manuso.
(f)10.15	Office Building Lease dated June 23, 2000 between the Registrant and Koll Dublin Corporate Center, L.P.
(d)10.16	Purchase and Sale Agreement dated as of September 30, 1996 between the Registrant and Warner-Lambert Company, a Delaware corporation.
(e)(q)10.17	Asset Purchase Agreement dated January 15, 1997 between the Registrant and Immunex Corporation, a Washington corporation.
(mm)(q)10.18	Drug Substance Validation and Supply Agreement dated July 2, 2003.
(g)(q)10.19	License Agreement between Inflazyme Pharmaceuticals Ltd. and the Registrant dated April 11, 1997.
(g)(q)10.20	Nonexclusive Supply Agreement between the Registrant and Yunnan Hande Technological Development Co. Ltd. dated May 7, 1997.
(h)10.21	Convertible Secured Note, Option and Warrant Purchase Agreement dated June 17, 1997 among the Registrant, Tako Ventures, LLC and, solely as to Sections 5.3 and 5.5 thereof, Lawrence J. Ellison (the "Tako Purchase Agreement").
(r)10.22	Amendment No. 1 to the Tako Purchase Agreement dated March 17, 1999.
(j)10.23	Form of Common Stock Purchase Agreement among the purchasers and the Registrant dated August 29, 1997.
(j)(q)10.24	License Agreement between Stehlin Foundation for Cancer Research and the Registrant dated September 3, 1997.
(k)(q)10.25	Supply Agreement dated October 20, 1997 between the Registrant and Warner-Lambert Company.
(t)10.26	Registration Rights Agreement dated November 23, 1998.
(o)10.27	Agreement and Plan of Reorganization by and among the Registrant, Royale Acquisition Corp., and Sparta Pharmaceuticals, Inc. dated January 18, 1999.
(r)10.28	Stock Purchase Agreement between the Registrant and Tako dated January 29, 1999.
(r)10.29	Standard Industrial/Commercial Multi-Tenant Lease dated February 12, 1999 between the Registrant and Sea Cliff Properties, a California general partnership (for the premises at 1075 Serpentine Lane, Pleasanton, California, Suite A).
(r)10.30	Standard Industrial/Commercial Multi-Tenant Lease dated February 12, 1999 between the Registrant and Sea Cliff Properties, a California general partnership (for the premises at 1075 Serpentine Lane, Pleasanton, California, Suite B).
(r)10.31	Secured Promissory Note Commitment dated March 25, 1999 issued by the Registrant to Tako Ventures LLC.
(r)10.32	Common Stock Purchase Warrant dated March 25, 1999.
(p)(q)10.33	Letter of Intent regarding Nipent Manufacturing.
(t)10.34	Common Stock Purchase Agreement dated November 23, 1998.
(q)(u)10.35	Know-How Transfer and Cooperation Agreement dated September 10, 1999 between the Registrant and Pharmachemie B.V.
(u)10.36	Agreement to Terminate and Release of Collateral dated September 30, 1999 between the Registrant and Tako Ventures, LLC.
(w)10.37	First Amendment to Agreement and Plan of Reorganization by and among the Registrant, Royale Acquisition Corp. and Sparta Pharmaceuticals, Inc. dated May 15, 1999.
(x)10.38	Form of Warrant Agreement dated August 12, 1999 between the Registrant and ChaseMellon Shareholder Services (including form of Common Stock Purchase Warrant).

Exhibit Number	Description of Document
(y)10.39	Amended & Restated Registration Rights Agreement dated September 1, 1999 between the Registrant and SMALLCAP World Fund, Inc.
(y)10.40	Purchase Agreement dated September 15, 1999 between the Registrant and The Tail Wind Fund Ltd., Carriage Partners, LLC, and LBI Group Inc.
(y)10.41	Supplement Agreement dated September 23, 1999 between the Registrant and the Tail Wind Fund, Ltd.
(y)10.42	Registration Rights Agreement dated September 15, 1999 between the Registrant and The Tail Wind Fund Ltd., Carriage Partners, LLC, and LBI Group Inc.
(y)10.43	Form of Warrant Agreement between Registrant and Clipperbay & Co.
(y)10.44	Form of Warrant Agreement between Registrant and The Tail Wind Fund Ltd., Carriage Partners, LLC, and LBI Group Inc.
(z)(q)10.45	Common Stock and Option Purchase Agreement, dated December 21, 1999 between the Registrant and Abbott Laboratories.
(z)10.46	Form Registration Rights Agreement.
(z)(q)10.47	Worldwide Sales, Distribution, and Development Agreement, dated December 21, 1999 between the Registrant and Abbott Laboratories.
(z)(q)10.48	U.S. Distribution Agreement, Dated December 21, 1999 between the Registrant and Abbott Laboratories.
(aa)10.49	Registration Rights Agreement dated December 15, 1999 between the Registrant and AVI BioPharma, Inc.
(aa)10.50	Subscription Agreement dated December 1, 1999 between the Registrant and AVI BioPharma, Inc.
(bb)10.51	Research Agreement (Camptothecin) dated November 15, 1999 between the Registrant and Clayton Foundation for Research.
(bb)10.52	Research Agreement (Paclitaxel) dated November 15, 1999 between the Registrant and Clayton Foundation for Research.
(bb)10.53	License Agreement (Camptothecin) dated November 15, 1999 between the Registrant and Research Development Foundation.
(bb)10.54	License Agreement (Paclitaxel) dated November 15, 1999 between the Registrant and Research Development Foundation.
(ee)(q)10.55	Amendment No. 1 to License Agreement dated November 1, 1999 between the Registrant and the Stehlin Foundation for Cancer Research.
(ee)10.56	United States of America Sales, Distribution, and Development Agreement dated April 4, 2000 between the Registrant and AVI BioPharma, Inc.
(ee)10.57	Common Stock and Warrant Purchase Agreement dated April 4, 2000 between the Registrant and AVI BioPharma, Inc.
(dd)10.58	Registration Rights Agreement dated April 4, 2000 between the registrant and AVI BioPharma, Inc.
(ee)10.59	Asset Purchase Agreement dated February 18, 2000 between the Registrant and AMUR Pharmaceuticals, Inc.
(ee)10.60	Patent and Intellectual Property Assignment Agreement dated September 27, 2000 between the Registrant and AMUR Pharmaceuticals, Inc.
(dd)10.61	Registration Rights Agreement dated September 27, 2000 between the registrant and AMUR Pharmaceuticals, Inc.
(dd)10.62	Warrant Agreement dated December 23, 1998 between the Registrant and Jesup & Lamont Securities Corporation.
(dd)10.63	Warrant Agreement dated October 4, 1999 between the Registrant and Paulson Investment Company, Inc.

Exhibit Number	Description of Document
(gg)(q)10.64	Supply and Distribution Agreement dated September 21, 2001 between the Registrant and EuroGen Pharmaceuticals Ltd.
(hh)10.65	Termination and Release Agreement dated March 4, 2002 between the Registrant and Abbott Laboratories.
(ii)10.66	Securities Purchase Agreement dated September 23, 2002 by and between the Registrant and the purchasers named therein.
(ii)10.67	Registration Rights Agreement dated September 23, 2002 by and between the Registrant and the purchasers named therein.
(ii)10.68	Form of Warrant dated September 24, 2002 issued to the purchasers under the Securities Purchase Agreement dated September 23, 2002.
(ii)10.69	Warrant dated September 24, 2002 issued Paul Revere LLC.
(jj)10.70	Registration Rights Agreement dated March 22, 2001 by and between the Registrant and The Kriegsman Group.
(jj)10.71	Warrant A Agreement dated March 22, 2001 by and between the Registrant and The Kriegsman Group.
(kk)10.72	Securities Purchase Agreement dated February 26, 2003 by and among the Registrant and the purchasers named therein.
(kk)10.73	Form of Senior Exchangeable/Convertible Note dated February 26, 2003 issued to the purchasers under the Securities Purchase Agreement dated February 26, 2003.
(kk)10.74	Registration Rights Agreement dated February 26, 2003 by and among the Registrant and the purchasers named therein.
(kk)10.75	Form of Warrant dated February 26, 2003 issued to the purchasers under the Securities Purchase Agreement dated February 26, 2003.
(kk)10.76	Pledge Agreement dated February 26, 2003 executed by the Registrant in favor of the purchasers under the Securities Purchase Agreement dated February 26, 2003.
(kk)10.77	Securities Account Control Agreement dated February 26, 2003 by and among the Registrant, the purchasers named therein, and Mellon Investor Services LLC.
(l)(q)10.78	Pentostatin Supply Agreement dated December 13, 2002 between the Registrant and Hauser Technical Services, Inc.
(m)(q)10.79	License Agreement dated February 13, 2001 between the Registrant and Peregrine Pharmaceuticals, Inc.
(nn)10.80	Securities Purchase Agreement dated June 24, 2003 by and among the Registrant and the purchasers named therein.
(nn)10.81	Form of Senior Convertible Note dated June 24, 2003 issued to the purchasers under the Securities Purchase Agreement dated June 24, 2003.
(nn)10.82	Registration Rights Agreement dated June 24, 2003 by and among the Registrant and the purchasers named therein.
(nn)10.83	Form of Warrant dated June 24, 2003 issued to the purchasers under the Securities Purchase Agreement dated June 24, 2003.
(nn)10.84	Amended and Restated Pledge Agreement dated June 24, 2003 executed by the Registrant in favor of the purchasers under the Securities Purchase Agreement dated June 24, 2003.
(nn)10.85	Amended and Restated Securities Account Control Agreement dated June 24, 2003 by and among the Registrant, the purchasers named therein and Mellon Investor Services LLC.
(nn)10.86	Collateral Account Agreement dated June 24, 2003.
(nn)10.87	Conversion and Amendment Agreement dated June 24, 2003.
(nn)10.88	Amended and Restated Convertible Notes dated June 24, 2003.
23.1	Consent of Ernst & Young LLP, Independent Auditors.

Exhibit Number	Description of Document
31.1	Certification of Chief Executive Officer under Section 302(a) of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer under Section 302(a) of the Sarbanes-Oxley Act of 2002
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(a) Incorporated by reference from the Registrant's Registration Statement on Form SB-2 (Reg. No. 333-476-LA) filed with the Securities and Exchange Commission January 18, 1996.

(b) Incorporated by reference from Amendment No. 1 to the Registrant's Registration Statement on Form SB-2 (Reg. No. 333-476-LA) filed with the Securities and Exchange Commission February 26, 1996.

(c) Incorporated by reference from the Registrant's Report on Form S-8 filed with the Securities and Exchange Commission on July 1, 1996.

(d) Incorporated by reference from the Registrant's Report on Form 8-K filed with the Securities and Exchange Commission on October 15, 1996.

(e) Incorporated by reference from the Registrant's Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 1997.

(f) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on August 11, 2000.

(g) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on May 15, 1997.

(h) Incorporated by reference from the Registrant's Report on Form 8-K filed with the Securities and Exchange Commission on July 2, 1997.

(i) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on August 13, 1997.

(j) Incorporated by reference from Amendment No. 2 on Form S-3 to the Registrant's Registration Statement on Form SB-2 (Reg. No. 333-476-LA) filed with the Securities and Exchange Commission on October 6, 1997.

(k) Incorporated by reference from the Registrant's Report on Form 8-K filed with the Securities and Exchange Commission on October 31, 1997.

(l) Incorporated by reference from the Registrant's Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2003.

(m) Incorporated by reference from the Registrant's Report on Form 10-K/A filed with the Securities and Exchange Commission on May 12, 2003.

(n) Incorporated by reference from the Registrant's Proxy Statement filed with the Securities and Exchange Commission on April 17, 2001.

(o) Incorporated by reference from the Registrant's Report on Form 8-K filed with the Securities and Exchange Commission on January 28, 1999.

(p) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on November 12, 1998.

(q) Confidential treatment has been previously granted for certain portions of these exhibits.

(r) Incorporated by reference from the Registrant's Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 1999.

(s) Indicates a management contract or compensatory plan or arrangement.

(t) Incorporated by reference from the Registrant's Report on Form 10-K/A filed with the Securities and Exchange Commission on May 14, 1999.

(u) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on November 15, 1999.

(v) Incorporated by reference from the Registrant's Registration Statement on Form S-8 (Reg. No. 333-87369) filed with the Securities and Exchange Commission on September 17, 1999.

(w) Incorporated by reference from the Registrant's Registration Statement on Form S-4 (Reg. No. 333-80517) filed with the Securities and Exchange Commission on June 11, 1999.

(x) Incorporated by reference from the Registrant's Report on Form 8-A filed with the Securities and Exchange Commission on August 12, 1999.

(y) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (Reg. No. 333-88051) filed with the Securities and Exchange Commission on September 29, 1999.

(z) Incorporated by reference from the Registrant's Report on Form 8-K/A dated December 22, 1999 filed with the Securities and Exchange Commission on January 7, 2000.

(aa) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (Reg. No. 333-95177) filed with the Securities and Exchange Commission on January 21, 2000.

(bb) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on May 15, 2002.

(cc) Incorporated by reference from the Registrant's Registration Statement on Form S-8 (Reg. No. 333-44736) filed with the Securities and Exchange Commission on August 29, 2000.

(dd) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (Reg. No. 333-52326) filed with the Securities and Exchange Commission on December 20, 2000.

(ee) Incorporated by reference from the Registrant's Report on Form 10-K filed with the Securities and Exchange Commission on March 23, 2001.

(ff) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on August 14, 2001.

(gg) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on November 14, 2001.

(hh) Incorporated by reference from the Registrant's Report on Form 8-K dated March 4, 2002 filed with the Securities and Exchange Commission on March 8, 2002.

(ii) Incorporated by reference from the Registrant's Report on Form 8-K dated September 23, 2002 filed with the Securities and Exchange Commission on October 1, 2002.

(jj) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (Reg. No. 333-100707) filed with the Securities and Exchange Commission on October 24, 2002.

(kk) Incorporated by reference from the Registrant's Report on Form 8-K dated February 26, 2003 filed with the Securities and Exchange Commission on February 27, 2003.

(ll) Incorporated by reference from the Registrant's Proxy Statement filed with the Securities and Exchange Commission on April 18, 2003.

(mm) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on August 14, 2003.

(nn) Incorporated by reference from the Registrant's Report on Form 8-K dated June 24, 2003 filed with the Securities and Exchange Commission on June 25, 2003.

(b) *Reports on Form 8-K.*

On November 4, 2003, SuperGen filed a report on Form 8-K dated November 4, 2003 relating to the results of its third fiscal quarter ended September 30, 2003. Under the Form 8-K, SuperGen furnished (not filed) pursuant to Item 12 under item 7 the press release relating to the results of its third fiscal quarter ended September 30, 2003.

(c) *Exhibits.* See Item 15(a) above.

(d) *Financial Statement Schedules.* See Item 15(a) above.

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

Board of Directors and Stockholders
SuperGen, Inc.

We have audited the accompanying consolidated balance sheets of SuperGen, Inc. as of December 31, 2003 and 2002, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of SuperGen, Inc. at December 31, 2003 and 2002 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States.

As discussed in Note 1 to the consolidated financial statements, in 2002 the Company changed its method of accounting for goodwill.

/s/ ERNST & YOUNG LLP

Palo Alto, California
February 18, 2004

SUPERGEN, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31, 2003	December 31, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,055	$ 7,241
Marketable securities	7,565	13,081
Restricted cash and investments	10,680	—
Accounts receivable, net	507	5,405
Due from related parties	319	402
Inventories	3,965	2,166
Prepaid financing costs	1,811	—
Prepaid expenses and other current assets	2,292	1,771
Total current assets	32,194	30,066
Marketable securities, non-current	1,957	2,100
Investment in stock of related parties	883	14,071
Due from related parties, non-current	118	390
Property, plant and equipment, net	4,420	5,443
Developed technology at cost, net	365	744
Goodwill, net	731	731
Other intangibles, net	111	269
Restricted cash and investments, non-current	13,927	3,489
Other assets	30	30
Total assets	$ 54,736	$ 57,333
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 3,558	$ 4,506
Convertible debt, current portion, net of discounts	13,593	—
Derivative liability	5,505	—
Payable to AVI BioPharma, Inc	565	421
Deferred revenue	—	1,000
Accrued payroll and employee benefits	2,193	1,621
Total current liabilities	25,414	7,548
Deferred rent	808	616
Deferred revenue, non-current	1,667	1,167
Total liabilities	27,889	9,331
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $.001 par value; 2,000,000 shares authorized; none outstanding	—	—
Common stock, $.001 par value; 150,000,000 shares authorized; 37,022,356 and 32,892,674 shares issued and outstanding at December 31, 2003 and 2002, respectively	37	33
Additional paid in capital	316,578	282,010
Deferred compensation	—	(47)
Accumulated other comprehensive loss	(3,100)	(796)
Accumulated deficit	(286,668)	(233,198)
Total stockholders' equity	26,847	48,002
Total liabilities and stockholders' equity	$ 54,736	$ 57,333

See accompanying notes to consolidated financial statements

SUPERGEN, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Year ended December 31,		
	2003	2002	2001
Revenues:			
Net sales revenue	$ 11,437	$ 14,188	$ 10,451
Other revenue	57	1,081	1,000
Total revenues	11,494	15,269	11,451
Operating expenses:			
Cost of sales	3,865	4,491	2,727
Research and development	26,312	29,895	47,833
Selling, general, and administrative	24,436	23,525	22,079
Total operating expenses	54,613	57,911	72,639
Loss from operations	(43,119)	(42,642)	(61,188)
Interest income	474	1,662	5,622
Interest expense	(3,981)	—	—
Amortization of deemed discount on convertible debt	(13,738)	—	—
Other than temporary decline in value of investments	—	(8,491)	—
Change in valuation of derivatives	6,894	—	—
Net loss	$(53,470)	$(49,471)	$(55,566)
Basic and diluted net loss per common share	$ (1.56)	$ (1.52)	$ (1.69)
Weighted average shares used in basic and diluted net loss per common share calculation	34,276	32,542	32,925

See accompanying notes to consolidated financial statements

SUPERGEN, INC.
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid in	Deferred	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Compensation	Gain (Loss)	Deficit	Total
Balances at January 1, 2001	33,384	33	287,677	(197)	(9,407)	(128,161)	149,945
Comprehensive loss:							
Net loss	—	—	—	—	—	(55,566)	(55,566)
Other comprehensive loss—Change in unrealized gain (loss) on investments	—	—	—	—	16,906	—	16,906
Comprehensive loss							(38,660)
Issuance of common stock upon exercise of warrants and stock options	158	—	1,428	—	—	—	1,428
Issuance of common stock to Abbott Laboratories	182	1	2,499	—	—	—	2,500
Issuance of common stock to Clayton Foundation in connection with research agreements	21	—	369	—	—	—	369
Issuance of common stock in connection with employee stock purchase plan	39	—	368	—	—	—	368
Compensation expense from stock option grants to consultants and vendors	—	—	890	—	—	—	890
Amortization of deferred compensation	—	—		75	—	—	75
Repurchase of common stock	(963)	(1)	(9,116)	—	—	—	(9,117)
Balances at December 31, 2001	32,821	33	284,115	(122)	7,499	(183,727)	107,798
Comprehensive loss:							
Net loss	—	—	—	—	—	(49,471)	(49,471)
Other than temporary decline in value of investments	—	—	—	—	8,491		8,491
Other comprehensive loss—Change in unrealized gain (loss) on investments	—	—	—	—	(16,786)	—	(16,786)
Comprehensive loss							(57,766)
Issuance of common stock upon exercise of warrants and stock options	9	—	80	—	—	—	80
Issuance of common stock in private placement, net of offering costs of $310	1,806	2	4,204	—	—	—	4,206
Issuance of common stock to Orphan Europe connection with research agreements	65	—	300	—	—	—	300
Issuance of common stock in connection with employee stock purchase plan	78	—	314	—	—	—	314
Compensation expense from stock option grants to consultants and vendors	—	—	169	—	—	—	169
Amortization of deferred compensation	—	—		75	—	—	75
Repurchase of common stock	(1,886)	(2)	(7,172)	—	—	—	(7,174)
Balances at December 31, 2002	32,893	$33	$282,010	$ (47)	$ (796)	$(233,198)	$ 48,002
Comprehensive loss:							
Net loss	—	—	—	—	—	(53,470)	(53,470)
Other comprehensive loss—Change in unrealized gain (loss) on investments	—	—	—	—	(2,304)	—	(2,304)
Comprehensive loss							(55,774)
Issuance of common stock upon conversion of senior convertible notes and payment of related interest	3,889	4	16,706	—	—	—	16,710
Issuance of common stock to Peregrine Pharmaceuticals in connection with license agreement	62	—	200	—	—	—	200
Issuance of common stock upon exercise of stock options, net of 39 shares surrendered as proceeds	361	—	1,108	—	—	—	1,108
Issuance of common stock in connection with employee stock purchase plan	83	—	308	—	—	—	308
Amortization of deferred compensation	—	—	—	6	—	—	6
Reversal of deferred compensation due to employee termination	—	—	(41)	41	—	—	—
Compensation expense from stock option and warrant grants to consultants and vendors	—	—	250	—	—	—	250
Compensation expense from issuance of warrants to placement agent of senior convertible notes	—	—	1,440	—	—	—	1,440
Beneficial conversion of warrants issued in connection with issuance of senior convertible notes	—	—	13,995	—	—	—	13,995
Compensation expense related to acceleration of stock option grants	—	—	1,493	—	—	—	1,493
Repurchase of common stock	(266)	—	(891)	—	—	—	(891)
Balances at December 31, 2003	37,022	$37	$316,578	$ —	$ (3,100)	$(286,668)	$ 26,847

See accompanying notes to consolidated financial statements

SUPERGEN, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year ended December 31,		
	2003	2002	2001
Operating activities:			
Net loss	$(53,470)	$(49,471)	$(55,566)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,191	1,324	1,138
Amortization of prepaid financing costs	3,064	—	—
Amortization of intangible assets	537	503	605
Amortization of deferred compensation	6	75	75
Amortization of deferred revenue	—	(1,000)	(1,000)
Amortization of deemed discount on convertible debt	13,738	—	—
Interest on convertible debt paid in common stock	460	—	—
Change in valuation of derivatives	(6,894)	—	—
Loss on disposal of property and equipment	—	—	132
Other than temporary decline in value of investments	—	8,491	—
Stock compensation for modification of employee options	1,493	—	—
Expense related to stock options and warrants granted to non-employees	250	169	890
Non-cash charge related to research or license agreements	200	300	369
Write-off of investment in EpiGenX	250	—	—
Cash option paid in modification of distribution agreement	(500)	—	—
Changes in operating assets and liabilities:			
Accounts receivable	4,898	(2,896)	(486)
Inventories	(1,799)	(333)	(185)
Prepaid expenses and other assets	(521)	(302)	1,154
Due from related parties	355	199	(620)
Other receivables	—	—	1,283
Restricted cash and investments	229	(122)	(155)
Accounts payable and other liabilities	(40)	(4,588)	2,531
Net cash used in operating activities	(36,553)	(47,651)	(49,835)
Investing activities:			
Purchases of marketable securities	(8,056)	(32,494)	(48,969)
Sales or maturities of marketable securities	13,627	72,732	53,124
Purchase of equity investments	—	—	(403)
Proceeds from convertible debt transferred to restricted cash and investments	(10,625)	—	—
Purchases of property and equipment	(168)	(422)	(2,177)
Net cash provided by (used in) investing activities	(5,222)	39,816	1,575
Financing activities:			
Proceeds from issuance of common stock, net of issuance costs	1,415	4,600	4,296
Prepaid financing costs	(3,435)	—	—
Proceeds from issuance of convertible debt	42,500	—	—
Repurchases of common stock	(891)	(7,174)	(9,117)
Net cash provided by (used in) financing activities	39,589	(2,574)	(4,821)
Net decrease in cash and cash equivalents	(2,186)	(10,409)	(53,081)
Cash and cash equivalents at beginning of period	7,241	17,650	70,731
Cash and cash equivalents at end of period	$ 5,055	$ 7,241	$ 17,650
Supplemental Disclosure of Non-Cash Financing Activities:			
Valuation of warrants issued to placement agent in connection with convertible debt transactions	$ 1,440	$ —	$ —
Beneficial conversion and deemed discount in connection with convertible debt	$ 26,395	$ —	$ —
Conversion of convertible notes into common stock	$ 16,250	$ —	$ —
Supplemental Disclosure of Cash Flow Information:			
Interest expense paid in cash during the year	$ 440	$ —	$ —

See accompanying notes to consolidated financial statements

1. Summary of Significant Accounting Policies

Description of Business

SuperGen, Inc. ("SuperGen", "we", "us" or the "Company") was incorporated in California in March 1991. We changed our state of incorporation to Delaware in 1997. We are a pharmaceutical company dedicated to the development and commercialization of oncology therapies for solid tumors, hematological malignancies and blood disorders. We operate in one industry segment.

Principles of Consolidation

Our consolidated financial statements include the accounts of EuroGen Pharmaceuticals Ltd. ("EuroGen"), Sparta Pharmaceuticals, Inc. ("Sparta") and three wholly-owned subsidiaries, which are immaterial. Intercompany accounts and transactions are eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results may differ from those estimates.

Fair Value of Financial Instruments

The fair values of our cash equivalents and marketable securities are based on quoted market prices. The fair value of accounts receivable, accounts payable, and convertible debt are considered to be representative of their respective fair values at December 31, 2003 and 2002.

Revenue Recognition

Our net sales relate principally to two pharmaceutical products, with Nipent sales representing 85% in 2003, 89% in 2002, and 93% in 2001. We recognize sales revenue upon shipment and related transfer of title to customers, and collectibility is reasonably assured, with allowances provided for bad debt and estimated returns. The allowances for bad debt and sales returns were $275,000, $118,000, and $108,000 at December 31, 2003, 2002, and 2001 respectively. Actual amounts for returns and allowances may differ from our estimates and such differences could be material to the consolidated financial statements. The provision for the allowances was $691,000 in 2003, $112,000 in 2002, and $265,000 in 2001.

Cash advance payments received in connection with distribution agreements or research grants are deferred and recognized ratably over the period of the respective agreements or until services are performed.

Our principal customers are clinics, hospitals and hospital buying groups in the United States and drug distributors and wholesalers in the United States and Europe. We do not require collateral from our customers.

Advertising Expense

Advertising costs are expensed as incurred. We incurred advertising costs of $319,000 in 2003, $756,000 in 2002, and $593,000 in 2001.

1. Summary of Significant Accounting Policies (Continued)

Research and Development

Research and development expenditures, including direct and allocated expenses, are charged to expense as incurred. These expenditures include salaries and employee-related expenses; fees paid to physicians, hospitals, or other research institutions for clinical and pre-clinical studies; fees paid to outside contractors for monitoring of clinical sites or collection and analysis of data; costs associated with the research and manufacture of clinical drug supplies; and payments made under technology license agreements prior to regulatory approval of drug candidates.

Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents include bank demand deposits, certificates of deposit, marketable securities with maturities of three months or less when purchased and money market funds which invest primarily in U.S. government obligations and commercial paper. These instruments are highly liquid and are subject to insignificant market risk.

Marketable securities consist of corporate or government debt securities and equity securities that have a readily ascertainable market value and are readily marketable. These investments are reported at fair value. All marketable securities are designated as available-for-sale, with unrealized gains and losses included in accumulated other comprehensive gain/loss in equity. A decline in the market value of a security below its cost that is deemed to be other than temporary is charged to earnings, and results in the establishment of a new cost basis for the security.

During the year ended December 31, 2002, we recorded a write-down of $8,491,000 related to other than temporary declines in the value of our marketable securities and investment in stock of related parties. We had no such write-downs in 2003 or 2001.

Restricted Cash and Investments

Under certain operating lease agreements and in connection with our convertible debt, we are required to set aside cash and/or investments as collateral. At December 31, 2003 and 2002, we had $24.6 million and $3.5 million of restricted cash and investments related to such agreements.

Equity Investments

Equity investments in securities without readily determinable fair value are carried at cost. These investments are included in marketable securities and investment in stock of related parties on the balance sheet. We periodically review those carried at cost and evaluate whether an impairment has occurred. During 2003, we determined that the value of an equity investment that we made in 2002 was impaired due to the poor financial condition of the company. As a result, the entire cost of the investment of $250,000 was charged to Selling, general and administrative expense in 2003. We believe the remaining equity investment amounts continue to be realizable.

1. Summary of Significant Accounting Policies (Continued)

Inventories

Inventories are stated at the lower of cost (using the first-in, first-out method) or market value. Inventories were as follows at December 31 (in thousands):

	2003	2002
Raw materials	$ 108	$ 126
Work in process	2,481	1,196
Finished goods	1,376	844
	$3,965	$2,166

Bulk materials for our primary pharmaceutical product must be purified at a United States Food and Drug Administration ("FDA") approved facility that meets stringent Good Manufacturing Practices standards. We currently use a single vendor to perform this manufacturing process using our own equipment located at the vendor's site. We have contracted with a separate vendor to manufacture the Nipent finished dosage at its approved facility. In addition, we store the majority of our bulk raw materials at a single storage location. Although there are a limited number of vendors who may be qualified to perform these services, we believe that other vendors could be engaged to provide similar services on comparable terms. However, the time required to locate and qualify other vendors or replace lost bulk inventory could cause a delay in manufacturing that might be financially and operationally disruptive. The parent company of the organization that performs the manufacturing of Nipent filed for reorganization under chapter 11 in April 2003. However, we do not believe that this reorganization will have any significant impact on our supply agreement and our ability to process Nipent, although there can be no assurance in this regard.

Property, Plant and Equipment

Property, plant and equipment are stated at cost. Depreciation of building, office and manufacturing equipment and furniture and fixtures is provided on a straight-line basis over the estimated original useful lives of the respective assets, which range from 3 to 31 years. Leasehold improvements are amortized over the shorter of the life of the lease or their estimated useful lives using the straight-line method.

Property, plant and equipment consist of the following at December 31 (in thousands):

	2003	2002
Land and building	$ 2,433	$ 2,433
Leasehold improvements	2,592	2,591
Equipment	962	903
Furniture and fixtures	3,491	3,386
Total property and equipment	9,478	9,313
Less accumulated depreciation and amortization	(5,058)	(3,870)
Property, plant and equipment, net	$ 4,420	$ 5,443

1. Summary of Significant Accounting Policies (Continued)

Developed Technology

Developed technology related to the acquisition of Nipent is being amortized to cost of sales on a units-manufactured basis over a period expected to approximate six years. Developed technology related to other acquired products is being amortized on a straight-line basis over five years. Cost basis of the developed technology was $1,936,000 at December 31, 2003 and 2002. Accumulated amortization was $1,571,000 and $1,192,000 at December 31, 2003 and 2002, respectively.

Goodwill

In July 2001, the Financial Accounting Standards Board ("FASB") issued Statements of Financial Accounting Standards No. 142 "Goodwill and Other Intangible Assets" ("SFAS 142"). Under SFAS 142, which became effective for fiscal years beginning after December 15, 2001, goodwill and indefinite lived intangible assets are no longer amortized but are reviewed annually (or more frequently if impairment indicators arise) for impairment. Intangible assets with finite useful lives will continue to be amortized over their respective useful lives. The standard also establishes specific guidance for testing impairment of goodwill and intangible assets with indefinite useful lives. We adopted SFAS 142 on January 1, 2002.

Goodwill no longer subject to amortization amounted to approximately $731,000 at December 31, 2003 and 2002. We monitor the carrying value of goodwill through the annual impairment tests and more frequently if the indicators of impairment arise.

The amortization expense and adjusted net loss for the years ended December 31 is as follows (in thousands, except per share amounts):

	Year ended December 31,		
	2003	2002	2001
Net loss as reported	$(53,470)	$(49,471)	$(55,566)
Add back: Goodwill amortization expense	—	—	273
Adjusted net loss	$(53,470)	$(49,471)	$(55,293)
Adjusted basic and diluted net loss per share	$ (1.56)	$ (1.52)	$ (1.68)
As reported basic and diluted net loss per share	$ (1.56)	$ (1.52)	$ (1.69)

Intangible Assets

Intangible assets, including trademarks, covenants not to compete, and customer lists, are stated at cost and amortized on a straight-line basis over their estimated useful lives of up to five years. Cost basis of intangible assets was $787,000 at December 31, 2003 and 2002. Accumulated amortization was $676,000 and $518,000 at December 31, 2003 and 2002, respectively.

The remaining net book value of our intangible assets was $111,000 as of December 31, 2003, which will be fully amortized in the year ending December 31, 2004.

Derivative Financial Instruments

We have issued warrants for common stock of another entity in connection with issuances of convertible debt. These warrants are considered to be a derivative financial instrument in accordance

1. Summary of Significant Accounting Policies (Continued)

with Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments," and are recorded at fair value. The changes in the fair value of the derivative financial instruments are recognized in current earnings in each reporting period.

Major Customers

Our major customers include a number of buying groups. The percentage of sales of each of these major customers to total net sales for the years ended December 31 were as follows:

	2003	2002	2001
Customer A	38%	9%	9%
Customer B	24	6	4
Customer C	15	21	12
Customer D	8	25	10
Customer E	—	15	23
Customer F	—	—	11
All others	15	24	31
Total	100%	100%	100%

Net Loss per Common Share

Basic and diluted net loss per common share is computed by dividing net loss by the weighted average number of shares outstanding during the year.

As we have reported operating losses each period since our inception, the effect of assuming the exercise of options and warrants and the assumed conversion of convertible debt would be anti-dilutive and, therefore, basic and diluted loss per share are the same. The anti-dilutive securities that we have omitted from the calculation of basic net loss per common share are disclosed in Notes 3 and 4.

Stock-Based Compensation

We account for stock issued to employees in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and comply with the disclosure provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123") and Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure" ("SFAS 148"). Under APB 25, compensation expense of fixed stock options is based on the difference, if any, on the date of the grant between the fair value of the our stock and the exercise price of the option. We account for stock issued to non-employees in accordance with the provisions of SFAS 123 and EITF No. 96-18, "Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services."

Under the intrinsic value method, when the exercise price of our employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized. The following table illustrates the pro forma effect on net loss and loss per share for the years ended

1. Summary of Significant Accounting Policies (Continued)

December 31, 2003, 2002 and 2001 had we applied the fair value method to account for stock-based awards to employees:

	Year ended December 31,		
	2003	2002	2001
Net loss, as reported	$(53,470)	$(49,471)	$(55,566)
Add: Stock-based employee compensation expense included in the determination of net loss, as reported	1,499	75	75
Deduct: Stock-based employee compensation expense that would have been included in the determination of net loss if the fair value method had been applied to all awards	(5,901)	(3,991)	(5,026)
Pro forma net loss	$(57,872)	$(53,387)	$(60,517)
Basic and diluted net loss per common share:			
As reported	$ (1.56)	$ (1.52)	$ (1.69)
Pro forma	$ (1.69)	$ (1.64)	$ (1.84)

Impairment of Long-lived Assets

We evaluate long-lived assets, other than goodwill, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable based on expected undiscounted cash flows attributable to that asset. The amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset. No impairment exists as of December 31, 2003.

Reclassification

We have reclassified market rate preferred securities balances at December 31, 2002 from cash equivalents to marketable securities to conform to the current year presentation.

Recent Accounting Pronouncements

In January 2003, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 46, "Consolidation of Variable Interest Entities," ("FIN 46"). FIN 46 clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. In December 2003, the FASB issued a revision to FIN 46, ("FIN 46R"). FIN 46R provides a broad deferral of the latest date by which all public entities must apply FIN 46 to certain variable interest entities to the first reporting period ending after March 15, 2004. We do not expect the adoption of FIN 46 to have a material impact on our financial position, cash flows or results of operations.

1. Summary of Significant Accounting Policies (Continued)

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity," which establishes standards for how an issuer of financial instruments classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or in some circumstances, as an asset) if, at inception, the monetary value of the obligation is based solely or predominantly on: (a) a fixed monetary amount known at inception, (b) variations in something other than the fair value of the issuer's equity shares or (c) variations inversely related to changes in the fair value of the issuer's equity shares. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 did not have an impact on our financial statements.

2. Available-for-Sale-Securities

The following is a summary of available-for-sale securities (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
At December 31, 2003				
U.S. corporate debt securities	$ 9,230	$ 17	$ (1)	$ 9,246
U.S. government debt securities	14,212	6	(1)	14,217
Marketable equity securities	14,427	247	(3,368)	11,306
Total	$37,869	$270	$(3,370)	$34,769
At December 31, 2002:				
U.S. corporate debt securities	$14,801	$ 57	$ —	$14,858
Foreign corporate debt securities	1,371	1	—	1,372
U.S. government debt securities	3,077	10	—	3,087
Marketable equity securities	14,679	9	(873)	13,815
Total	$33,928	$ 77	$ (873)	$33,132

2. Available-for-Sale-Securities (Continued)

The available-for-sale securities are classified on the balance sheet as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
At December 31, 2003				
Amounts included in cash and cash equivalents	$ 3,643	$ —	$ —	$ 3,643
Marketable securities, current	7,555	11	(1)	7,565
Amounts included in investment in stock of related parties	265	—	(62)	203
Amounts included in restricted cash and investments	24,705	3	(3,307)	21,401
Marketable securities, non-current	1,701	256	—	1,957
Total	$37,869	$270	$(3,370)	$34,769
At December 31, 2002				
Amounts included in cash and cash equivalents	$ 5,530	$ —	$ —	$ 5,530
Marketable securities, current	12,026	55	—	12,081
Investment in stock of related parties	14,294	—	(873)	13,421
Marketable securities, non-current	2,078	22	—	2,100
Total	$33,928	$ 77	$ (873)	$33,132

Available-for-sale securities at December 31, by contractual maturity, are shown below (in thousands):

	Fair Value	
	2003	2002
Debt securities		
Due in one year or less	$21,887	$17,611
Due after one year through three years	1,576	1,706
	23,463	19,317
Marketable equity securities	11,306	13,815
Total	$34,769	$33,132

Realized gains and losses on the sale of available-for-sale securities for the years ended December 31, 2003, 2002, and 2001 were not material.

During the year ended December 31, 2002, we recorded write-downs of $8,491,000 related to other than temporary declines in the value of our marketable securities and investment in stock of related parties. We had no such write-downs in 2003 or 2001.

3. Stockholders' Equity

Stock Repurchase Plan

In September 2000, the SuperGen Board of Directors authorized a stock repurchase plan to acquire, in the open market, an aggregate of up to 1,000,000 shares of our common stock, at prices not to exceed $22.00 per share or $20,000,000 in total. In March 2001 and September 2002, the Board

3. Stockholders' Equity (Continued)

authorized increases in the number of shares to be acquired under the repurchase plan, but maintained the $20,000,000 repurchase total.

During the year ended December 31, 2003, we repurchased 266,000 shares of our common stock at a cost, net of commissions, of $891,000. During the year ended December 31, 2002, we repurchased 1,886,000 shares of our common stock at a cost, net of commissions, of $7,174,000. Since inception of the stock repurchase plan, we have repurchased 3,299,000 shares of our common stock at a cost, net of commissions, of $19,579,000. All shares repurchased have been retired.

Private Placement

In September 2002, we entered into a Securities Purchase Agreement and Registration Rights Agreement with several investors for the private placement of shares of our common stock and warrants. In connection with these agreements, we issued 1,806,400 shares of our common stock to the investors at a per share price of $2.50, for an aggregate amount of $4,516,000, and issued warrants to the investors for the purchase of the same number of shares. The warrants have the following characteristics: (i) 1,204,269 of the warrants have an exercise price of $4.00 and the other 602,131 of the warrants have an exercise price of $5.00 per share, (ii) the warrants will be exercisable for a term of four years, (iii) the exercise prices of the warrants will be subject to adjustment so that, if we issue any shares of our common stock (including options and warrants, with certain exceptions), at a price that is lower than the respective exercise prices, then the respective exercise prices will be reduced to each such lower price, provided, however, that after 540 days of issuance of the warrants, the respective exercise prices shall not be reduced to less than $2.50, and (iv) after two years, the warrants will be redeemable by SuperGen, at our option, at $0.25 per warrant, if the shares of our common stock are trading at above 200% of the respective exercise prices for twenty consecutive days.

As compensation to the placement agent, we paid the placement agent $310,000 in cash and issued a four-year warrant to an affiliate of the placement agent for the purchase of 118,000 shares of our common stock at an exercise price of $3.00 per share. Using the Black-Scholes valuation method, we calculated the value of these warrants to be $176,000, which was treated as part of the cost of the offering.

3. Stockholders' Equity (Continued)

Warrants

At December 31, 2003, warrants to purchase the following shares of our common stock were outstanding:

Number of Shares	Exercise Price	Issue Date	Expiration Date
1,924,400	$ 3.00–5.00	2002	2006
551,419	4.00–6.00	2003	2007
1,997,500	5.00	2003	2008
230,000	10.35	1997	2007
200,000	10.47	2001	2006
100,000	10.47	2003	2007
500,000	11.00	1998	2004
1,045,000	13.50	1997	2007
86,489	18.00–22.075	1999	2004
200,000	40.00	2000	2004
6,834,808			

In September 2000, we acquired all of the intellectual property of AMUR Pharmaceuticals, Inc. in exchange for 37,795 shares of our common stock and two-year warrants to purchase 200,000 shares of our common stock at $40.00 per share. In September 2002, we extended the terms of the two-year warrants to purchase 200,000 shares of our common stock by two additional years. We calculated the Black-Scholes valuation of this warrant extension at $2,000, which we charged to Research and development expense in 2002.

In March 2001, we entered into agreements with a consultant to perform certain financial consulting and public relations services. In connection with these agreements, we issued the consultant a three-year warrant to purchase 200,000 shares of unregistered common stock at an exercise price of $10.47. We calculated the value of the warrant at $758,000 using the Black-Scholes valuation model, utilizing an expected volatility of 0.762, risk-free interest rate of 5.88%, and expected life of three years. The warrant was fully vested in 2001, and the value of the warrant of $758,000 was charged to Selling, general and administrative expense in 2001. In February 2003, we extended the expiration date of this warrant by three years, and issued the consultant another four-year warrant to purchase 100,000 shares of unregistered common stock at an exercise price of $10.47. We calculated the value of the warrant extension and the new warrant grant at $249,000, using an expected volatility of 0.844, risk-free interest rate of 4.12%, and expected life of two additional years for the extended warrant and four years for the new warrant. The value of our stock on the date of the extension and new grant was $3.00. The value of the warrant extension and new warrant grant was charged to Selling, general and administrative expense in 2003.

3. Stockholders' Equity (Continued)

Stock Reserved for Future Issuance

At December 31, 2003, we have reserved shares of common stock for future issuance as follows:

Stock options outstanding	5,326,349
Stock options available for grant	2,694,033
Warrants to purchase common stock	6,834,808
Shares available for Employee Stock Purchase Plan	39,870
Shares issuable upon conversion or payment of convertible debt	4,515,671
	19,410,731

4. *Stock Option Plans*

We have 10,263,000 shares of common stock authorized for issuance upon the grant of incentive stock options or nonstatutory stock options to employees, directors, and consultants under our stock option plans. The number of shares to be purchased, their price, and the terms of payment are determined by the Company's Board of Directors, provided that the exercise price for incentive stock options cannot be less than the fair market value on the date of grant. The options granted generally expire ten years after the date of grant and become exercisable at such times and under such conditions as determined by the Board of Directors (generally over a four or five year period).

A summary of the Company's stock option activity and related information follows:

	Options Outstanding			
	Number of Shares	Weighted Average Exercise Price	Options Exercisable	Weighted Average Fair Value At Grant Date
Balance at January 1, 2001	3,290,145	$14.36	2,164,066	
Granted at fair value	688,450	9.64		$6.32
Granted at greater than fair value	24,000	19.30		5.51
Exercised	(141,533)	9.49		
Forfeited	(155,100)	17.63		
Balance at December 31, 2001	3,705,962	13.57	2,679,490	
Granted at fair value	1,314,300	3.71		2.53
Exercised	(833)	6.50		
Forfeited	(483,972)	17.62		
Balance at December 31, 2002	4,535,457	10.28	3,188,761	
Granted at fair value	1,405,450	4.61		3.28
Exercised	(400,488)	3.80		
Forfeited	(214,070)	8.61		
Balance at December 31, 2003	5,326,349	$ 9.34	4,080,995	

4. Stock Option Plans (Continued)

Information concerning the options outstanding at December 31, 2003 is as follows:

	Options outstanding			Options exercisable	
Range	Number	Weighted average exercise price	Weighted average remaining contractual life	Number exercisable	Weighted average exercise price
$ 1.75 to $ 4.03	1,044,177	$ 2.79	8.30	690,754	$ 3.02
4.05 to 4.57	971,511	4.38	9.31	428,398	4.36
4.96 to 7.03	1,018,669	5.92	4.20	922,316	5.92
7.06 to 12.63	1,047,415	10.42	6.64	868,177	10.44
12.69 to 68.00	1,244,577	20.59	5.01	1,171,350	20.43
$ 1.75 to $68.00	5,326,349	$ 9.34	6.60	4,080,995	$10.39

Pro forma information regarding the results of operations and net loss per share (Note 1) is determined as if we had accounted for our employee stock options using the fair value method. Under this method, the fair value of each option granted is estimated on the date of grant using the Black-Scholes option valuation model. We estimated the fair value for these options at the date of grant using the Black-Scholes model with the following assumptions:

	Year ended December 31,		
	2003	2002	2001
Risk-free interest rate	2.73%	4.17%	5.48%
Dividend yield	—	—	—
Expected volatility	0.865	0.834	0.760
Expected life (in years)	5.0	5.0	5.0

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting requirements and are fully transferable. Employee stock options have characteristics significantly different than those of traded options. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility and changes in the subjective input assumptions can materially affect the estimate of fair value of an employee stock option. Therefore, in our opinion, existing option valuation models do not necessarily provide a reliable single measure of the fair value of our employee stock options.

During the year ended December 31, 1999, in connection with the grant of certain stock options to employees and officers, we recorded deferred stock compensation for financial statement reporting purposes of $947,000, representing the difference between the exercise price and the deemed fair value of our common stock for financial reporting purposes on the date the stock options were granted. Deferred compensation is included as a component of stockholders' equity and is being amortized to expense on a straight line basis over four years, the vesting period of the options. During the years ended December 31, 2003, 2002, and 2001, we recorded amortization of deferred stock compensation expense of $6,000, $75,000, and $75,000, respectively. During the year ended December 31, 2003, we reversed $41,000 of deferred compensation, representing the value of unvested stock options forfeited upon the departure of an officer of the Company.

During the year ended December 31, 2003, we recorded a non cash charge of $1.5 million for stock compensation related to the modification and acceleration of options associated with the change in status or departure of certain Company management.

5. Convertible Debt Financing Transactions

February Convertible Debt Transaction

On February 26, 2003 we entered into a Securities Purchase Agreement for the private placement of Senior Exchangeable Convertible Notes ("February Notes") in the principal amount of $21.25 million and related warrants.

The February Notes accrue interest at a rate of 4% per year. The principal amount of the February Notes was repayable in four equal quarterly installments beginning nine months after the closing of the transactions. The February Notes were, at the option of the investors, in whole or in part, (a) convertible into shares of our common stock at a fixed conversion price of $4.25 per share, and (b) exchangeable for up to 2,634,211 shares of common stock of AVI BioPharma, Inc. ("AVI") that we own (the "AVI Shares") at a fixed exchange price of $5.00 per share. We may pay interest due under the February Notes in shares of our common stock at a price tied to the then market price, and subject to certain conditions, we could have also elected to pay principal due under the February Notes in shares of our common stock and AVI Shares at prices tied to the then market price of our common stock and AVI common stock, respectively. Subject to certain conditions, at any time after the first anniversary of the effectiveness of the registration statement covering the resale of our shares of common stock, all of the outstanding February Notes would have been redeemable by us for a cash redemption price at 120% of par plus accrued and unpaid interest. Upon a Change of Control (as defined under the February Notes), the holders will have certain redemption rights, and we could have also redeemed the February Notes, in each case subject to certain conditions and provided that, in the event of our redemption, we would have issued to the holders of the February Notes certain warrants exercisable for the securities of the acquiring entity and the AVI Shares. Our exchange obligations under the February Notes were secured by a pledge of the AVI Shares.

In accordance with Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments" ("SFAS 133"), we were required to separate and account for, as an embedded derivative, the option feature that allowed holders of the February Notes to receive a portion of the principal and interest in the AVI Shares at $5.00 per share. As an embedded derivative instrument, the exchangeable feature was measured at fair value and reflected as a liability. Changes in the fair value of the derivative have been recognized in earnings. We determined the fair value of the exchange feature with respect to the AVI Shares to be $2,337,000 at February 26, 2003, which was calculated as an American style written put option on 2,634,211 AVI shares, with a strike of $5.00, expiring on the related principal and interest payment dates through August 2004. This amount was allocated from the proceeds of the February Notes to the derivative liability at February 26, 2003. The exchangeable feature was embedded in the February Notes to increase the appeal of our private placement to institutional investors and to reduce the related interest and principal payments. The convertible feature on our own SuperGen shares associated with the February Notes does not qualify as embedded derivatives under SFAS 133.

In connection with the issuance of the February Notes, we issued warrants to the note holders for the purchase of an aggregate of 1,997,500 shares of SuperGen common stock. These warrants will be exercisable for a term of five years at an exercise price of $5.00 per share. We valued these warrants using the Black-Scholes method with the following assumptions: a risk-free interest rate of 4%, volatility of 0.85, and a dividend yield of 0%. This resulted in an assigned value of $4,614,000. The proceeds from the February Notes of $21,250,000, less the embedded derivative, were allocated between the convertible instrument and the warrants on a relative fair value basis, which resulted in a fair value of $3,783,000 allocated to the warrants as a deemed discount on the convertible debt. In

5. Convertible Debt Financing Transactions (Continued)

connection with the issuance of the February Notes and related warrants, we also recorded $3,000,000 related to the beneficial conversion feature on the February Notes, because the effective conversion price of the convertible debt was less than the fair value of the common stock on the date of issuance. The total amount of the deemed discount on the February Notes as a result of the warrant issuance, the embedded derivative, and the beneficial conversion feature amounted to $9,120,000. The debt discount was being amortized over 21 months, the term of the February Notes.

Also in connection with the issuance of the February Notes, we paid legal fees of approximately $370,000. In addition, as compensation to the placement agent, we paid the placement agent $1,477,500 in cash and issued a four-year warrant to an affiliate of the placement agent for the purchase of 363,125 shares of our common stock at an exercise price of $4.00 per share. The warrant issued to the placement agent was assigned a value of $813,400, using the Black-Scholes method with the following assumptions: a risk-free interest rate of 4%; volatility of 0.85; and a dividend yield of 0%. The total of the legal fees, placement agent cash fee, and placement agent warrant valuation was $2,661,000, which we recorded as prepaid financing costs. This amount was being amortized over 21 months, the term of the February Notes, to interest expense.

June Convertible Debt Transaction and February Notes Restructuring

On June 24, 2003, we closed a private placement transaction in which we issued Senior Convertible Notes ("June Notes") in the aggregate principal amount of $21.25 million, to the same holders of our outstanding February Notes. The June Notes are payable in four equal quarterly installments beginning March 31, 2004, and accrue interest at a rate of 4% per year. Pursuant to the terms of the June Notes, the note holders may elect to convert, at any time prior to maturity, their June Notes into shares of our common stock at a fixed price $6.36, which was calculated based on the trading prices of our common stock for the twenty trading days after issuance of the June Notes. We may also elect to pay the principal and interest then due under the June Notes, subject to certain conditions, through the issuance of shares of our common stock at a conversion price equal to: (i) with respect to the interest payment, 95% of the arithmetic average of the weighted average price of our common stock on each of the five consecutive trading days immediately preceding payment, and (ii) with respect to the principal payment, as of any date of determination, at 90% of the arithmetic average of the weighted average price of our common stock on any fifteen trading days designated by the note holders during the twenty trading days immediately preceding such date.

While the full amount of the $21,250,000 proceeds from the June Notes was transferred to SuperGen, $10,625,000 of such funds were placed into an interest bearing collateral account, and not available for our use until release. Absent certain defaults by us, $5,312,500 (one-half of the $10,625,000) will be available to us on March 24, 2004, and the remaining $5,312,500 will be available on June 24, 2004.

Concurrent with the issuance of the June Notes, we restructured our outstanding February Notes. Pursuant to the restructuring, the holders of the February Notes converted half of the principal amount ($10,625,000) plus accrued and unpaid interest thereon into 2,508,000 shares of our common stock at the fixed conversion price of $4.25, thereby causing the remaining $10,625,000 principal amount of the outstanding February Notes to have a final maturity date of February 26, 2004. The remaining February Notes have been amended to remove the feature permitting the holders to exchange such notes into the AVI Shares at an exchange price of $5.00, and to remove our ability to use the AVI Shares valued at market at the time of repayment to repay the outstanding principal amount.

5. Convertible Debt Financing Transactions (Continued)

In addition, in connection with the issuance of the June Notes and the restructuring of the February Notes, we issued to the note holders warrants to purchase the 2,634,211 AVI Shares at an exercise price of $5.00 per share. The warrants represent a derivative under SFAS 133 that must be recorded at fair value. Changes in the fair value of the derivative are recognized in earnings. We determined the fair value of the warrants at June 24, 2003, using the Black-Scholes method with the following assumptions: a risk-free interest rate of 2.26%, volatility of 0.92, and a dividend yield of 0%. This resulted in an assigned value of $10,063,000. At December 31, 2003, the fair value of the derivative had declined to $5,505,000 and is recorded as a current liability on the balance sheet. Changes in the valuation of this derivative have been charged to income or expense under the caption "Change in valuation of derivatives." The embedded derivative associated with the February Notes had a value $2,504,000 on June 24, 2003. Since the ability to exchange the notes into shares of AVI was eliminated in our June 2003 convertible debt transaction, the entire derivative value of $2,504,000 was taken to income and is also included in "Change in valuation of derivatives."

The proceeds from the June Notes of $21,250,000 were allocated between the convertible instrument and the derivative on a relative fair value basis, which resulted in a fair value of $11,187,000 allocated to the convertible debt. In connection with the issuance of the June Notes, we also recorded $7,213,000 related to the beneficial conversion feature on the June Notes, because the effective conversion price of the convertible debt was less than the fair value of the common stock on the date of issuance. The total amount of the deemed discount on the June Notes as a result of the warrant issuance and the beneficial conversion feature amounted to $17,275,000. The debt discount is being amortized over 18 months, the term of the June Notes. Since half of the principal amount of the debt related to the February Notes had been converted into our common stock, half of the debt discount of $9,120,000 relating to the February Notes was charged to expense in the second quarter 2003. At December 31, 2003, the remaining unamortized balance of the deemed discount on the convertible debt relating to both the February Notes and June Notes was $12,657,000.

Also in connection with the issuance of the June Notes, we paid legal fees of approximately $74,000. In addition, as compensation to the placement agent, we paid the placement agent $1,452,500 in cash and issued a four-year warrant to an affiliate of the placement agent for the purchase of 188,294 shares of our common stock at an exercise price of $6.00 per share. The warrant issued to the placement agent was assigned a value of $627,000, using the Black-Scholes method with the following assumptions: a risk-free interest rate of 2%; volatility of 0.85; and a dividend yield of 0%. The total of the legal fees, placement agent cash fee, and placement agent warrant valuation was $2,154,000, which we recorded as prepaid financing costs. This amount is being amortized over 18 months, the term of the June Notes, to interest expense. Since half of the principal amount of the debt related to the February Notes had been converted into our common stock, half of the prepaid financing costs of $2,661,000 relating to the February Notes was charged to interest expense in the second quarter 2003. At December 31, 2003, the unamortized balance of prepaid financing costs relating to both the February Notes and June Notes was $1,811,000.

5. Convertible Debt Financing Transactions (Continued)

In connection with the issuance of the warrants to acquire the AVI Shares, we pledged the AVI Shares into a collateral account. The fair value of the AVI shares of $10,721,000 is included in the accompanying consolidated December 31, 2003 balance sheet under Restricted cash and investments. We continue to hold all of the pledged AVI shares and continue to reflect changes in those share values in accumulated other comprehensive loss.

6. Acquisition Activity

Peregrine Pharmaceuticals—VEGF License

In February 2001, we completed a transaction to license a platform drug-targeting technology known as Vascular Targeting Agent ("VTA") from Peregrine Pharmaceuticals, formerly known as Techniclone Corp. The licensed technology is specifically related to Vascular Endothelial Growth Factor ("VEGF"). The agreement required an up-front payment of $600,000, which included the acquisition of 150,000 shares of Peregrine common stock valued at $253,000. These shares are carried as part of Marketable Securities—non-current. The remaining $347,000 of the payment was recorded to Research and development expense.

The terms of the agreement require that we pay milestone payments and royalties to Peregrine based on the net revenues of any drugs commercialized using the VEGF technology. These payments could ultimately total $8 million. No milestone or royalty payments have been made under the agreement to date. In addition, we are required to pay Peregrine an annual license fee of $200,000 per year until the first filing of an Investigational New Drug Application utilizing the licensed patents. During the year ended December 31, 2003, we paid the annual license fee of $200,000 to Peregrine in shares of our common stock. We issued Peregrine 61,653 shares of unregistered stock, which was calculated based on the average price of our common stock during the 30-day period preceding the payment date. During the year ended December 31, 2002, we paid Peregrine $200,000 in cash in connection with this agreement. The annual license fees paid to Peregrine were charged to Research and development expense.

Clayton Foundation for Research—Inhaled Drugs

In December 1999, we entered into a licensing and research agreement with the Clayton Foundation for Research and its technology transfer organization, Research Development Foundation. Under the terms of the licensing agreement, we acquired worldwide rights to inhaled versions of formulations of camptothecins, including Orathecin™, and taxanes, including paclitaxel. The license rights were acquired for 28,799 shares of common stock with an aggregate value of $916,000, which we charged to research and development in 1999. The license agreement contained certain guarantees related to the price of our stock issued in the acquisition. In January 2001, since the value of our stock had declined, we issued the Research Development Foundation an additional 21,210 shares of our stock. These shares were valued at $369,000, which we charged to research and development expense in 2001.

The Clayton Foundation agreed to perform the research in exchange for 36,130 shares of common stock, which we valued at $1,191,000. As the research had not started at December 31, 1999, the total was included in prepaid expenses and other assets at that date. The amount was charged to research and development expense in 2000. In December 2000, we issued an additional 46,613 shares of common stock to the Clayton Foundation in connection with the second year of research. These shares

6. Acquisition Activity (Continued)

were valued at $740,000 and the total was included in prepaid expenses at December 31, 2000, and charged to research and development in 2001.

During 2003 and 2002, we paid the Research Development Foundation $100,000 and $274,000, respectively, in connection with the research agreement, which we charged to Research and development expense.

Orathecin

In September 1997, we acquired exclusive worldwide rights to a patented anticancer compound, Orathecin, from the Stehlin Foundation for Cancer Research ("Stehlin"). We also agreed to make monthly cash payments to Stehlin of $100,000 until the earlier of the date of FDA marketing approval of Orathecin or four years. Our agreement with Stehlin also calls for additional payments in SuperGen common stock upon the achievement of specified milestones and royalties on any product sales.

In November 1999, we amended our agreement with Stehlin to broaden the definition of licensed compounds to include certain analogues of Orathecin. Under this amendment, we increased our monthly cash payments to $200,000 for 2000 and 2001 and are required to seek commercial applications for Orathecin. We were required to pay Stehlin approximately $9.6 million for research and must make cash royalty payments and cash or stock milestone payments to Stehlin as we develop and commercialize Orathecin. In accordance with these agreements, we paid Stehlin $800,000 in 2003, $1,200,000 in 2002, and $2,400,000 in 2001. Through December 31, 2003, we have paid Stehlin all of the $9.6 million required for research, but have not yet paid any milestone or royalty payments.

7. Termination of Agreements with Abbott Laboratories

In December 1999, we entered into two agreements with Abbott Laboratories ("Abbott"), a Common Stock and Option Purchase Agreement and a Worldwide Sales, Distribution and Development Agreement relating to Orathecin. Under these agreements, Abbott was to invest in shares of our common stock and would participate with us in the marketing and distribution of Orathecin. We would have co-promoted Orathecin with Abbott in the United States and Abbott would have had exclusive rights to market Orathecin outside of the United States. In connection with these agreements, Abbott made a $26.5 million equity investment in January 2000 and a $2.5 million equity milestone payment in July 2001.

On March 4, 2002, SuperGen and Abbott mutually terminated the Common Stock and Option Purchase Agreement and the Worldwide Sales, Distribution and Development Agreement. We regained all marketing rights to Orathecin worldwide In connection with this termination agreement, we agreed to reimburse Abbott for development work they completed on our behalf and paid Abbott $880,000 in March 2002 and $370,000 in 2003.

In December 1999, we also entered into a Nipent distribution agreement with Abbott, which is still in effect. Beginning March 1, 2000, Abbott became the exclusive U.S. distributor of Nipent for a period of five years. We retain U.S. marketing rights for Nipent. Under this agreement, Abbott made a $5 million cash payment to the Company in January 2000. This amount is included in deferred revenue and was recognized as other revenue through December 2002.

In March 2003, we entered into an agreement with Abbott that allows us to terminate the Nipent distribution agreement, for a stated fee that decreases over time to $1.5 million at March 2005. As part

7. Termination of Agreements with Abbott Laboratories (Continued)

of the agreement, we paid Abbott $500,000 for the right to terminate the Nipent distribution agreement at our option. The $500,000 has been recorded as a reduction of the deferred revenue we initially received from Abbott for the distribution rights, and we have stopped amortizing the remaining deferred revenue, which was $1,667,000 at December 31, 2003, to account for the termination fee we may pay to Abbott.

The unamortized balances of $1,667,000 and $2,167,000 are included in current and non-current deferred revenue at December 31, 2003 and 2002, respectively.

8. Related Party Transactions

EuroGen Pharmaceuticals Ltd.

In September 2001, we entered into a Supply and Distribution Agreement with EuroGen Pharmaceuticals Ltd., a company incorporated and registered in England and Wales. Under the agreement, we granted EuroGen the exclusive European and South African rights to promote and sell certain of our existing generic and other products or compounds. The agreement also establishes a process for granting EuroGen rights to sell additional products in Europe and South Africa, subject to our compliance with our other existing licensing and distribution arrangements. After complying with these existing obligations, we will be required to offer EuroGen the option to obtain European and South African rights to our future products. EuroGen will seek and pay for all necessary regulatory approvals and authorizations necessary for the commercial sale of the products in the territories where they market and sell the products. During 2001 we had loaned EuroGen $260,000 under a line of credit arrangement designed to cover start-up expenses. During 2002, we advanced an additional $646,000 to EuroGen to fund its operations. In December 2002, all but one of the other investors in EuroGen withdrew their ownership interests in the entity, and we became 95% owners of EuroGen. The remaining 5% is owned by Larry Johnson, the President and CEO of EuroGen. The amounts advanced to EuroGen, including the amounts advanced in 2001, totaling $906,000 were charged to Selling, general, and administrative expense in 2002. In 2003 the results of EuroGen are included in our consolidated operations and $325,000 has been included in Selling, general, and administrative expenses.

KineMed, Inc.

In November 2001, we made an equity investment of $150,000 to acquire 100,000 shares of Series A Convertible Preferred stock of KineMed, Inc. ("KineMed"), a start-up biotech company. In March 2003, we made an additional equity investment of $30,000 to acquire an additional 15,000 shares. The president and chief executive officer of KineMed is a former director of SuperGen. Our current president and chief executive officer is a member of the board of directors of KineMed. We have accounted for this investment under the cost method as our ownership is less than 20% of KineMed's outstanding shares. This investment is included on the balance sheet in Investment in stock of related parties.

AVI BioPharma, Inc.

In December 1999, we entered into an agreement with AVI BioPharma, Inc. At the time, the chief executive officer of AVI was a member of our Board of Directors. He later resigned from our Board in May 2002. The former president and chief executive officer of SuperGen was and continues to be a

8. Related Party Transactions (Continued)

member of the Board of Directors of AVI. Under the terms of the agreement, we acquired one million shares of AVI common stock, which amounted to approximately 7.5% of AVI's outstanding common stock, for $2.5 million cash and 100,000 shares of our common stock at $28.25 per share. We also acquired exclusive negotiating rights for the United States market for Avicine, AVI's proprietary cancer vaccine currently in late-stage clinical testing against a variety of solid tumors. Avicine is a non-toxic immunotherapy that neutralizes the effect of a tumor-associated antigen on cancer cells, while stimulating the body's immune system to react against the foreign tumor.

In July 2000, we finalized an agreement with AVI to obtain the U.S. marketing rights for Avicine. We issued 347,826 shares of our common stock along with $5 million in cash to AVI as payment for our investment, in exchange for 1,684,211 shares of AVI common stock. As part of this agreement, we obtained the right of first discussion to all of AVI's oncology compounds and an option to acquire an additional 10% of AVI's common stock for $35.625 per share. This option is exercisable for a three-year period commencing on the earlier of the date the FDA accepts the NDA submitted for Avicine or the date on which the closing price of AVI's common stock exceeds the option exercise price. We have accounted for the investment in AVI under the cost method as our ownership is less than 20% of AVI's outstanding shares and is classified as available-for-sale. No value has been ascribed to the option as neither of the measurements have been achieved as of December 31, 2003.

Avicine will require significant additional expenditures to complete the clinical development necessary to gain marketing approval from the FDA and equivalent foreign regulatory agencies. As part of this agreement, we are obligated to make additional payments to AVI based on successful achievement of developmental, regulatory approval, and commercialization milestones over the next several years that could total $80 million. In 2001, we recorded $1.2 million in research and development expenses relating to our share of the development costs for Avicine, which was paid in 2002. In 2003 and 2002, we recorded $144,000 and $421,000, respectively, in research and development expenses for Avicine. At December 31, 2003, the sum of the 2003 and 2002 expenses, or $565,000, was still payable and is presented on the balance sheet as Payable to AVI BioPharma, Inc.

AMUR Pharmaceuticals, Inc.

Two SuperGen directors were formerly directors of AMUR Pharmaceuticals, Inc., a privately-held company conducting research and development work partially funded by SuperGen. The president of AMUR performed consulting services for SuperGen and was paid $15,000 in 2003, $180,000 in 2002, and $180,000 in 2001 for these consulting services.

In September 2000, we acquired all of the intellectual property of AMUR in exchange for 37,795 shares of our common stock and two-year warrants to purchase 200,000 shares of our common stock at $40.00 per share (see Note 3). During 2002, these warrants were extended for two additional years.

Quark Biotech, Inc.

Two SuperGen director/stockholders are directors and stockholders of Quark Biotech, Inc. ("QBI"), a privately-held development stage biotechnology company. In June 1997, we made an equity investment of $500,000 in QBI's preferred stock, which represents less than 1% of the company's outstanding shares as of December 31, 2001. Our investment in QBI is carried at cost and is included in "Investment in stock of related parties."

8. Related Party Transactions (Continued)

In January 2002, we subleased a portion of our laboratory space to QBI. During 2003 and 2002, we collected $56,000 and $123,000, respectively, in sublease income from QBI. The initial term of the sublease expired on December 31, 2002, but we continued to sublease the space to QBI on a month-to-month basis until August 2003.

The Kriegsman Group

In March 2001, we retained The Kriegsman Group to render advice and assistance with respect to financial public relations and promotions. On July 25, 2002, our former president and chief executive officer and current board member became a member of the board of directors of CytRx Corp. Steven Kriegsman, the president of The Kriegsman Group, is also a significant shareholder and president and chief executive officer of CytRx Corp. See Note 3 for discussion of warrants granted to the Kriegsman Group and the accounting treatment of the warrants. We also paid The Kriegsman Group consulting fees of $220,000 in 2003, $240,000 in 2002, and $232,500 in 2001.

Other

At December 31, 2003, we owned 10% of a privately-held company performing research and development work almost exclusively for SuperGen as well as selling SuperGen certain research supplies. We paid this company $371,000 in 2003 and $360,000 in 2002, and 2001 for services and supplies. We carry our investment in this company at no value.

At December 31, 2003 and 2002, we have $437,000 and $792,000, respectively, in receivables due from related parties. The receivables are primarily advances or loans to employees. $250,000 of the balance at December 31, 2003 relates to a loan from an officer that is past due. Payment of the loan was due on December 31, 2003 under its original terms. The loan is expected to be repaid in 2004.

9. Commitments and Contingencies

We lease our primary administrative facility under a 10 year non-cancellable operating lease, which may be renewed for an additional five-year period. The terms of the lease require us to establish and maintain two irrevocable and unconditional letters of credit to secure our obligations under the lease. The financial institution issuing the letters of credit requires us to collateralize our potential obligations under the lease by assigning to the institution approximately $3.2 million in certificates of deposit. The certificates of deposit are included in the balance sheet under "Restricted cash." Upon achievement of certain milestones and the passage of time, the amounts of the letters of credit are subject to reduction or elimination.

We are also leasing additional office space in a building adjacent to our laboratory facility under two leases which both terminate in 2006. Half of the space has been subleased under a non-cancellable lease terminating at the same time as our master lease. The other half of the space has been subleased through June 2004.

9. Commitments and Contingencies (Continued)

Future minimum rentals and sublease income under all operating leases with terms greater than one year are as follows (in thousands):

	Minimum rental obligations	Sublease income
Year ending December 31,		
2004	$ 2,266	$248
2005	2,326	177
2006	2,175	91
2007	2,107	—
2008 and thereafter	6,637	—
	$15,511	$516

Rent expense was $1,985,000 in 2003, $1,948,000 in 2002, and $2,090,000 in 2001. These amounts were net of sublease income of $393,000 in 2003, $450,000 in 2002, and $237,000 in 2001.

We have entered into technology license agreements allowing us access to certain technologies. These agreements generally require royalty payments based upon the sale of approved products incorporating the technology under license. No sales of such products have occurred as of December 31, 2003.

We have also entered into manufacturing and service agreements for certain manufacturing services, the supply of research materials and the performance of specified research studies. These agreements require payments based upon the performance of the manufacturing entity, delivery of the research materials or the completion of the studies. No such payments were required as of December 31, 2003.

10. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets are as follows (in thousands):

	December 31,	
	2003	2002
Deferred Tax Assets:		
Net operating loss carryforwards	$ 97,030	$ 81,137
Purchased in-process technology	3,415	2,086
Research and development credit carryforwards	7,971	6,833
Capitalized research and development	6,683	6,452
Other	4,919	1,339
	120,018	97,847
Valuation allowance	(114,862)	(97,847)
Deferred tax assets	$ 5,156	$ —
Deferred Tax Liabilities:		
Amortization of Debt Discount	5,156	—
Deferred tax liabilities	$ 5,156	—
Net Deferred Tax Assets	$ —	$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $17,015,000 during 2003, by $14,668,000 during 2002, and by $21,919,000 during 2001.

As of December 31, 2003 we have net operating loss carryforwards for federal income tax purposes of approximately $267,553,000 which expire in the years 2005 through 2023, and federal research and development credit carryforwards of approximately $4,955,000, which expire in the years 2007 through 2023.

Utilization of our net operating loss carryforwards may be subject to substantial annual limitations due to ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation could result in the expiration of the net operating losses before utilization.

11. Employee Benefit Plans

We have adopted a 401(k) Profit Sharing Plan (the "401(k) Plan") for all eligible employees with over six months of service. We may be obligated to make contributions to the plan to comply with statutory requirements. Voluntary employee contributions to the 401(k) Plan may be matched 50% by the Company, up to 3% of each participant's annual compensation. Our expense relating to contributions made to employee accounts under the 401(k) Plan was approximately $300,000 in 2003, $297,000 in 2002, and $294,000 in 2001.

11. Employee Benefit Plans (Continued)

In 1998 we established the 1998 Employee Stock Purchase Plan ("ESPP"), and a total of 300,000 shares of Common Stock are reserved for issuance under the plan. Employees participating in the ESPP are granted the right to purchase shares of common stock at a price per share that is the lower of 85% of the fair market value of a share of Common Stock on the first day of an offering period, or 85% of the fair market value of a share of Common Stock on the last day of that offering period.

In 2003, we issued 37,065 and 45,746 shares through the ESPP at $3.59 and $3.82, respectively. In 2002, we issued 44,097 and 33,606 shares through the ESPP at $4.46 and $3.48, respectively. In 2001, we issued 16,936 and 22,650 shares through the ESPP at $10.07 and $8.71, respectively. As of December 31, 2003, 39,870 shares are reserved for future issuance under the ESPP.

12. Quarterly Financial Data (Unaudited)

Following is a summary of the quarterly results of operations for the years ended December 31, 2003 and 2002:

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(Amounts in thousands, except per share data)			
2003				
Net sales	$ 2,176	$ 4,096	$ 4,419	$ 746
Cost of sales	754	1,585	1,023	504
Net loss	(11,666)	(12,468)	(10,503)	(18,834)
Basic and diluted net loss per share	(0.35)	(0.38)	(0.30)	(0.52)
2002				
Net sales	$ 1,344	$ 5,614	$ 657	$ 6,573
Cost of sales	728	1,738	161	1,864
Net loss	(12,081)	(10,945)	(20,112)	(6,333)
Basic and diluted net loss per share	(0.37)	(0.34)	(0.63)	(0.19)

13. Legal Proceedings

On April 14, 2003, John R. Blum filed a class action complaint entitled *John R. Blum v. SuperGen, Inc., et al.,* No. C 03-1576 in the U.S. District Court for the Northern District of California, against us and our former president and chief executive officer alleging violations of the Exchange Act and seeking unspecified damages. Subsequently, six similar actions were filed in the same court. Each of the complaints purported to be a class action lawsuit brought on behalf of persons who purchased or otherwise acquired our common stock during the period of April 18, 2000 through March 13, 2003, inclusive (except that one complaint specified the period as between April 18, 2000 through March 14, 2003). The complaints alleged that during such period, we issued materially false and misleading statements and failed to disclose certain key information regarding Mitozytrex. The complaints did not specify the amount of damages sought. In July 2003, each of the plaintiffs elected to voluntarily dismiss their respective complaints without prejudice. Each of the dismissals has been approved and entered by the court.

We are not currently subject to any pending material legal proceedings.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, on this 4th day of March 2004.

SUPERGEN, INC.

By: /s/ JAMES S.J. MANUSO

James S.J. Manuso
Chief Executive Officer, President and Director

POWER OF ATTORNEY

We, the undersigned officers and directors of SuperGen, Inc. hereby constitute and appoint James S.J. Manuso and Michael Molkentin, and each of them individually, our true and lawful attorney-in-fact, with full power of substitution, to sign for us and in our names in the capacities indicated below any amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or their substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ JAMES S.J. MANUSO (James S.J. Manuso)	Chief Executive Officer, President and Director (Principal Executive Officer)	March 4, 2004
/s/ MICHAEL MOLKENTIN (Michael Molkentin)	Chief Financial Officer (Principal Financial and Accounting Officer)	March 4, 2004
/s/ CHARLES CASAMENTO (Charles Casamento)	Director	March 4, 2004
/s/ THOMAS V. GIRARDI (Thomas V. Girardi)	Director	March 4, 2004
/s/ WALTER J. LACK (Walter J. Lack)	Director	March 4, 2004
/s/ JOSEPH RUBINFELD (Joseph Rubinfeld)	Director	March 4, 2004
/s/ MICHAEL YOUNG (Michael Young)	Director	March 4, 2004

EXHIBIT 23.1

Consent of Ernst & Young LLP, Independent Auditors

We consent to the incorporation by reference in Form S-8 and the Post-Effective Amendment No. 1 to the Form S-8 (Registration No. 333-07295) pertaining to the 1993 Stock Option Plan, 1996 Director's Stock Option Plan and Employees and Consultants Stock Option Agreement/Plan, the Form S-8 (Registration No. 333-58303) pertaining to the 1993 Stock Option Plan, and 1998 Employee Stock Purchase Plan, the Form S-8 (Registration No. 333-87369) pertaining to the 1993 Stock Option Plan, the Form S-8 (Registration No. 333-44736) pertaining to the 1993 Stock Option Plan, the Form S-8 (Registration No. 333-86644) pertaining to the 1996 Directors' Stock Option Plan and 1998 Employee Stock Purchase Plan, the Post-Effective Amendment No. 6 on Form S-3 to Form SB-2 (Form SB-2 No. 333-476-LA) for the registration of 4,477,402 shares of common stock and 328,500 warrants to purchase common stock, the Form S-3 (Registration No. 333-88051) for the registration of 2,014,036 shares of common stock, the Form S-3 (Registration No. 333-52326) for the registration of 697,533 shares of common stock, the Form S-3 (Registration No. 333-95177) for the registration of 136,130 shares of common stock, the Form S-3 (Registration No. 333-100707) for the registration of 3,930,800 shares of common stock, the Form S-3 (Registration No. 333-104255) for the registration of 11,549,219 shares of common stock, the Form S-3 (Registration No. 333-107301) for the registration of 5,004,000 shares of common stock, and the Form S-8 (Registration No. 333-110152) pertaining to the 2003 Stock Plan and related prospectuses, of our report dated February 18, 2004, with respect to the consolidated financial statements of SuperGen, Inc. included in the Annual Report on Form 10-K for the year ended December 31, 2003.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 2, 2004

EXHIBIT 31.1

Certification under Section 302(a) of the Sarbanes-Oxley Act of 2002

I, James S.J. Manuso, certify that:

1. I have reviewed this annual report on Form 10-K of SuperGen, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
   b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
   c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 4, 2004

By: /s/ JAMES S.J. MANUSO

James S.J. Manuso
President and Chief Executive Officer
(Principal Executive Officer)

STOCKHOLDER INFORMATION

BOARD OF DIRECTORS

James S. J. Manuso, Ph.D.
Chairman, President and Chief Executive Officer
SuperGen, Inc.

Charles J. Casamento
Chairman and Chief Executive Officer
Questcor Pharmaceuticals

Thomas V. Girardi
Senior Partner
Girardi & Keese

Walter T. Lack
Managing Partner
Pettit Kohn, Lipscomb & Lack

Lester Lyon Rubinfeld, Ph.D.
Co-Founder, Chief Scientist and Chairman Emeritus, SuperGen, Inc.

Michael D. Young, M.D., Ph.D.
Chairman and Chief Scientific Officer
Strategic Healthcare Development, LLC

SENIOR MANAGEMENT TEAM

James S. J. Manuso, Ph.D.
President and Chief Executive Officer

Edward L. Jacobs
Chief Operating Officer

Michael Molkentin
Chief Financial Officer and Corporate Secretary

Audrey Jakubowski, Ph.D.
Senior Vice President, Regulatory Affairs

Karl L. Mettinger, M.D., Ph.D.
Senior Vice President, Chief Medical Officer

Larry Johnson
President and Chief Executive Officer, EuroGen (United Kingdom)

Timothy L. Enns
Vice President, Investor Relations and Business Development

Sanjeev Redkar, Ph.D.
Vice President, Pharmaceutical Development and Manufacturing

Michael V. McCullar, Ph.D.
Executive Director, Strategic Planning and Project Management

CORPORATE HEADQUARTERS

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4140 Dublin Blvd.
Suite 200
Dublin, CA 94568
800.353.1075 Tel
925.560.0101 Fax

INDEPENDENT AUDITORS

Ernst & Young
Building 1, Suite 200
1001 Page Mill Road
Palo Alto, CA 94304

TRANSFER AGENT

Mellon Investor Services, LLC
Overpeck Center
85 Challenger Road
Ridgefield Park, NJ 07660
800.522.6645 Tel
www.melloninvestor.com

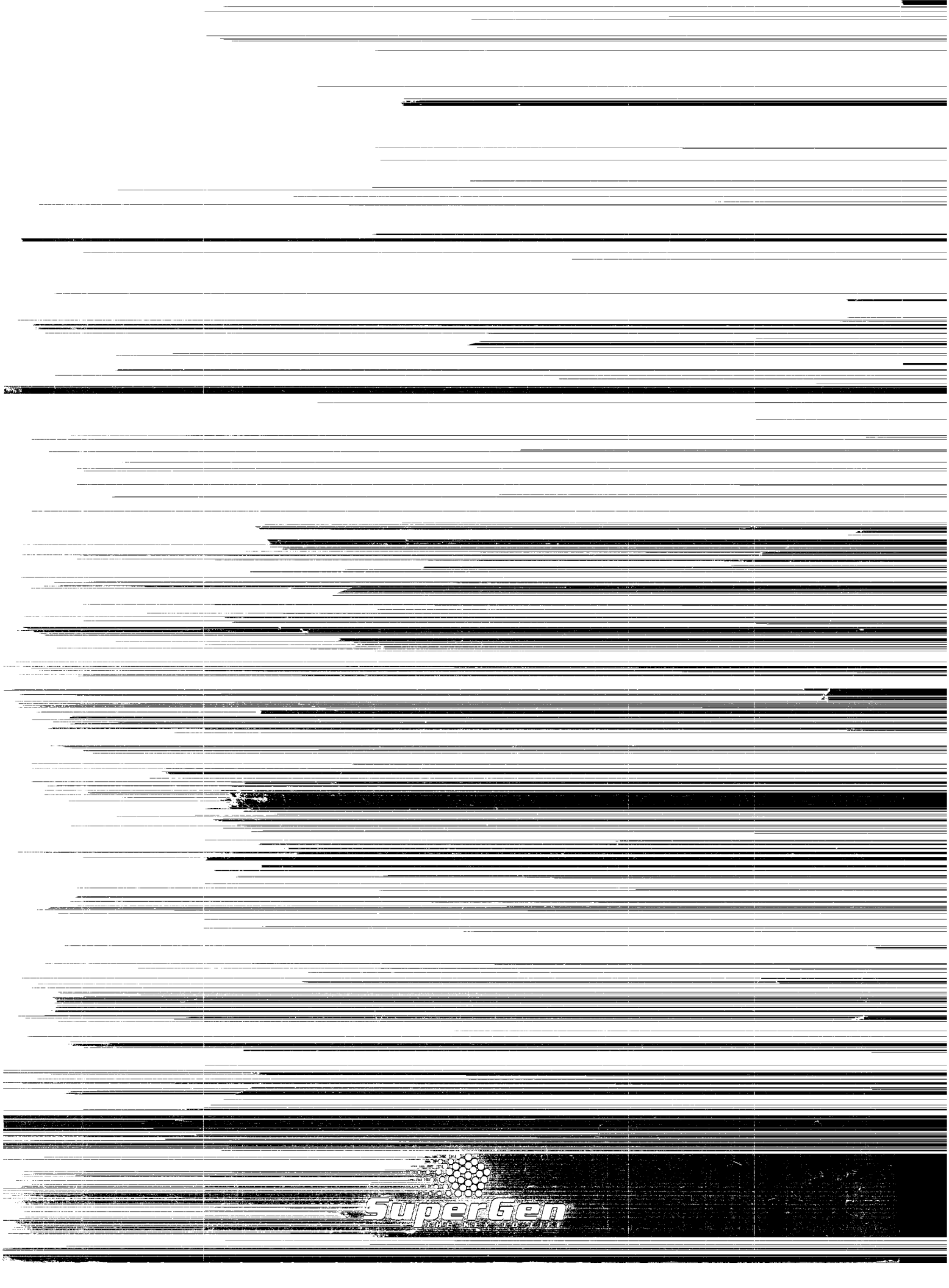
ANNUAL MEETING

The annual meeting of stockholders will be held from 2:00 p.m. to 5:00 p.m. on May 6, at SuperGen's corporate headquarters.

NASDAQ: SUPG

For information about the company, stockholders and other interested parties may contact the Investor Relations Department at the company headquarters, or visit the company website at www.supergen.com.

Inquiries regarding stock certificates, transfer requirements, address changes and related matters should be directed to the Transfer Agent at the address given above.


SuperGen
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